IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: 37697-0039

Applicant(s):	William H. HARRIS *et al.*	Confirmation No.: 8865
Serial No.:	10/040,900	Examiner: Paul B. Prebilic
Filing Date:	January 9, 2002	Group Art Unit: 3738
Title:	POLYETHYLENE HIP JOINT PROSTHESIS WITH EXTENDED RANGE OF MOTION	

DECLARATION OF DR. WILLIAM H. HARRIS

I, William H. Harris, do hereby declare as follows:

1. I received my M.D. degree from the University of Pennsylvania in 1951. I have been on the staff of the Massachusetts General Hospital ("MGH") since 1960. I became the Chief of the Hip and Implant Unit in the Department of Orthopedic Surgery at the MGH in 1974, and became the Director of the Orthopedic Biomechanics and Biomaterials Laboratory of the MGH in 1982. I have been using ultrahigh molecular weight polyethylene ("UHMWPE") in total hip replacements and related surgeries since 1969. I have performed about 3,000 hip replacements during the ensuing decades. I have been involved in research in the field of total hip replacements for over 30 years, and have authored or co-authored over 400 peer-reviewed publications. Among other awards, I have received the Charnley Award of the Hip Society on three separate occasions, the Muriel E. Mueller Lifetime Achievement in Orthopedic Surgery Award of the Mueller Foundation, the Dr. Marion Ropes Award of the Massachusetts Chapter of the Arthritis Foundation, and the H.A. Paul Award of the International Society for Technology and Arthroplasty. I am a co-inventor named in the captioned patent application.

2. I understand that the claims in the captioned patent application have been rejected over various combinations of Graham *et al.* (U.S. Patent No. 5,549,700); Townley *et al.* (U.S. Patent No. 6,096,084); McKellop *et al.* (U.S. Patent No. 6,165,220); DeCarlo *et al.* (U.S. Patent No. 4,524,467); and Teinturier *et al.* (U.S.

Patent No. 4,385,405). In order to address these rejections, I believe that a brief discussion of the history of hip replacement would be useful.

3. The present invention has satisfied a long-felt but previously unmet need. Throughout the history of total hip replacement, from its very inception in 1959, the experience with all plastic materials that were tried for total hip replacement surgery (including polytetrafluoroethylene, ultra high molecular weight polyethylene, delrin and others), a single dominant issue existed which was the major influence on the wear of the plastic. That single issue was head size. Small femoral heads articulating against conventional UHMWPE wore less – large femoral heads articulating against conventional UHMWPE wore more. See for example, Elfick *et al. J Arthroplasty.* 1998, 13(3):291-5 (Exhibit 1); Livermore *et al., J Bone Joint Surg Am.* 1990, 72(4):518-28 (Exhibit 2).

In their early attempts at hip replacement, several investigators tried large head size in order to provide extended range of motion and reduced the likelihood of dislocation. However, experience demonstrated that volumetric wear rate increased with respect to size of femoral head. For example, 32 mm diameter femoral head components showed greater wear than smaller heads. See for example, Livermore *et al., J Bone Joint Surg Am.* 1990, 72(4):518-28 (Exhibit 2); Clarke *et al. Proc Inst Mech Eng [H].* 1997, 211(1):25-36 (Exhibit 3); Hirakawa *et al. J Biomed Mater Res.* 1997, 36(4):529-35 (Exhibit 4); Elfick *et al. J Arthroplasty.* 1998, 13(3):291-5) (Exhibit 1). In response, the field went to smaller head sizes, such as 26 mm and 30 mm. See, for example, Affatato *et al. Chir Organi Mov.* 1997, 82(4):393-9 (Exhibit 5), using conventional uncrosslinked UHMWPE. Charnley went to diameters as small as 22mm, and most others in the field also went to such smaller head sizes. See the attached excerpt from Charnley, Low Friction Arthroplasty of the Hip Theory and Practice, (Springer-Verlag. Berlin 1979) (Exhibit 6).

The 32 mm head size fell into disfavor as increasing evidence made clear the fact that the 32 mm head size had a higher volumetric wear rate, and a higher incidence of periprosthetic osteolysis. Accordingly, the field continued to avoid larger heads. See, for example, Manley *et al. J Bone Joint Surg Am.* 1998, 80(8):1175-85 (Exhibit 7); Affatato *et al. Chir Organi Mov.* 1997, 82(4):393-9 (Exhibit

5). Because larger head diameter could not be utilized due to wear, investigators alternatively optimized head-neck diameter ratio in an attempt to enhance range of motion. See, for example, Chandler *et al. Clin Orthop.* 1982, (166):284-91 (Exhibit 8).

4. The use of a larger head, such as a head size of 32 mm or higher, was then considered adverse and the field continued to avoid larger heads for years. I have published collaborative research articles that demonstrate the fact. See for example, Schmalzried *et al.* Abstract of presentation at the forty-first annual meeting of the Orthopaedic Research Society, February 13-16, 1995, Orlando, Fl (Exhibit 9); and Schmalzried *et al. The Proceedings of the Institution of Mechanical Engineers*, part H, Journal of Engineering in Medicine 1999 2 13(2):p.147-153 (Exhibit 10). Prosthesis used in the above research included mostly 26 mm heads and occasionally 28 mm heads (See Exhibit 10, page 149, left column, lines 12-14). As the legend of figure 1 explains: "[t]he large diameter of these components [referring to surface replacement] results in a volumetric wear of polyethylene that is 4 - 10 times higher than that produced by a conventional 28 mm diameter bearing for the equivalent number of cycles."

5. The claimed invention has solved, among other things, a long-felt but previously unmet need by providing thinner and wear-resistant polymer cups (see for example, the captioned application at page 2 lines 4-26), which made it possible to make polymeric cups that accommodate femur heads of 35 mm or greater while minimizing wear. The ability to accommodate larger heads while achieving wear resistance provides greater range of motion, decreased potential of wear-related dislocation, and extended lifetime of the prosthesis (see the captioned application at page 3, lines 20-25, for example).

6. Regarding the Examiner's allegation of the instant invention being taught or suggested by Graham *et al.* and/or Townley *et al.* in view of McKellop *et al*, I submit the following points in rebuttal:

a. The McKellop patent (US 6,165,220) does not provide a femur head of diameter larger than 32 mm and there is no mention of using femoral head

diameters larger than 32 mm. McKellop discloses "surface-crosslinked UHMWPE acetabular cups of 32 mm" (see column 17, lines 3-4), however, does not describe acetabular cup having diameter of 35 mm or more, nor that the "crosslinked UHMWPE" could be used to make wear resistant acetabular cups that can accommodate femur head of diameter larger than 32 mm. According to McKellop, "PE powder is placed in an implant mold and compression molded using methods known in the art to a slight oversize of the I.D. [inner diameter] to allow for the addition of a crosslinked layer" (see Column 9, lines 65-67). That is, McKellop reinforces the bias in the filed for smaller heads and teaches away from making acetabular cup having diameter larger than 32 mm (such as 35 mm) using the "crosslinked UHMWPE."

The McKellop patent does not disclose that this "crosslinked UHMWPE" material would have a relationship to femoral head diameter nor that specifically the relationship of head size to wear would be the exact opposite of the experience of the field with these heads sizes and many others over the previous four decades. Furthermore, in order to accommodate a head of 35 mm or greater, it is necessary to minimize cup thickness (see, for example, the captioned application at page 2, lines 4-26; page 15, lines 8-29; page 16, line 7 through page 7, line 23). McKellop uses UHMWPE material of 8 mm thickness (see, for example, column 11, lines 58-58; column 12, lines 38-39), and does not suggest to minimize cup thickness by using cups of about 1 mm to about 5 mm in thickness. Moreover, McKellop does not address cup thickness in relation to head diameter.

b. Graham *et al.* and Townley *et al.* do not rectify deficiencies of McKellop because:

i. Graham uses conventional UHMWPE to make polymeric cups (See col. 4, lines 61-64). In contrast, the instant invention uses cross-linked UHMWPE polymer (See for example, the captioned application at page 3, lines 11-15). While Graham describes various mechanical modification of polymeric cups to improve wear resistance (see for example, col. 3, lines 1-13 and lines 53-97 to col. 4, lines 1-2), it does not provide any teaching to improve chemical and mechanical properties, such as cross-linking by irradiation in combination with melting. Graham also does not provide

any diameter of the cup or the head that the cup can embrace. Therefore, Graham patent does not provide any teaching on polymeric cup thickness in relation to head diameter; and

ii. Townley does not disclose large ball diameter, ovoid head, and varying degrees of movement. Rather, Townley discloses "ceramic ball and socket for prosthetic hip" and optionally "articular cup" made of conventional uncrosslinked UHMWPE (see col. 4, lines 24-38). Townley patent also does not provide any teaching on polymeric cup thickness in relation to head diameter.

7. Regarding the Examiner's allegation that certain claims are unpatentable over Townley and McKellop in combination with DeCarlo or Teinturier, I submit the following points in rebuttal:

First, Townley and McKellop have serious deficiencies, described above, which are not rectified by DeCarlo and/or Teinturier. DeCarlo describes cups with greater degrees of freedom and Teinturier discloses contact surfaces for ovoid heads. However, DeCarlo and Teinturier do not provide any motivation to obtain irradiated wear resistant polymeric cups that can accommodate heads of 35 mm or greater. The invention of the captioned application provided for the first time a medically-acceptable femur cup larger than 32 mm (such as a cup that is 35 mm in diameter) by allowing for thinner cups. Therefore, the combination of Townley *et al.* and McKellop *et al.* and DeCarlo *et al.*, or Teinturier *et al.* does not teach or suggest the claimed invention because these references do not describe the use of the irradiated wear resistant polymer cups of a minimized thickness.

8. In sum, McKellop describes polymeric cups no larger than 32 mm and provides no information on thickness of the cup. Graham, Townley, DeCarlo, and Teinturier indicate use of conventional polymeric materials that are not wear resistant. The combination of references applied by the examiner do not provide cross-linked polymeric cup with 35 mm or greater with thickness of about 1 mm to about 5 mm. Rather, McKellop, Graham, Townley, DeCarlo, and Teinturier repeat the past reliance on small heads or the past failures of large heads, as noted in previous sections above.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

July 2, 2004

W Harris

William H. Harris

1: J Arthroplasty. 1998 Apr;13(3):291-5. Related Articles, L

J Arthroplasty

Wear in retrieved acetabular components: effect of femoral hea radius and patient parameters.

Elfick AP, Hall RM, Pinder IM, Unsworth A.

Centre for Biomedical Engineering, School of Engineering, University of Durham, United Kingdom.

Forty-seven explanted Porous Coated Anatomic (PCA, Howmedica, Rutherford, NJ) cementless acetabular components were acquired at revision surgery. All the components articulated against CoCrMo femoral heads of 32 mm diameter. The penetration depth and angle were measured using the shadowgraph technique. The wear volume was then calculated using Kabo's formula. Using weighted linear regression analysis, the mean penetration rate and mean volumetric wear rate were calculated to be 0.23 (SE, 0.03) mm3/y and 96 (SE, 13) mm3/y, respectively. The creep component was not found to significantly different from zero. The clinical wear factor, k(clinical), for this cohort was also calculated using linear regression analysis but with the assumption that creep was zero. The value found, k(clinical) = 1.93 (SE, 0.29 10(-6) mm3/N-m, was similar to those in previous studies involving cemente joints with a 22-mm femoral head diameter. The similar k(clinical) values of these substantially different joint types suggest that the high volumetric wear rate for the PCA joint can be attributed entirely to its larger head size and the younger, more active, patient profile. Fixation technique and metal backing seem not to influence the rate of wear.

PMID: 9590640 [PubMed - indexed for MEDLINE]

Display Abstract Show: 20 Sort Send to Text

1: J Bone Joint Surg Am. 1990 Apr;72(4):518-28. Related Articles, L

Effect of femoral head size on wear of the polyethylene acetabul: component.

Livermore J, Ilstrup D, Morrey B.

Department of Orthopedics, Mayo Clinic, Rochester, Minnesota 55905.

A technique was developed to determine the wear of the acetabular compone of a total hip replacement by examination of standardized initial and follow-ı radiographs. Three hundred and eighty-five hips were followed for at least 9. years after replacement. The least amount and rate of linear wear were associated with use of a femoral head that had a diameter of twenty-eight millimeters (p less than 0.001). The greatest amount and mean rate of linear wear occurred with twenty-two-millimeter components, but these differences were not statistically significant. The greatest volumetric wear and mean rate rate of volumetric wear were seen with thirty-two-millimeter components (p less than 0.001). A wider radiolucent line in acetabular Zone 1 was associate with use of the thirty-two-millimeter head. The amounts of resorption of the proximal part of the femoral neck and of lysis of the proximal part of the fem both correlated positively with the extent of linear and volumetric wear; this suggests an association between the amount of debris from wear and these changes in the femoral neck and proximal part of the femur.

PMID: 2324138 [PubMed - indexed for MEDLINE]

1: Proc Inst Mech Eng [H]. 1997;211(1):25-36.

Charnley wear model for validation of hip simulators--ball diameter versus polytetrafluoroethylene and polyethylene wear.

Clarke IC, Good V, Anissian L, Gustafson A.

Howard and Irene Peterson Tribology Laboratory, Loma Linda University Medical Center, California, United States of America.

Wear rates of polytetrafluoroethylene (PTFE) and polyethylene cups were compared in 9-channel and 12-channel simulators, using serum lubrication a gravimetric techniques for wear assessment. Cobalt-chromium (CoCr) and alumina ceramic femoral heads in 22-42 mm diameter range were used to validate simulator wear rates against clinical data. This was also the first stud of three femoral head sizes evaluated concurrently in a simulator (with three replicate specimens) and also the first report in which any wear experiments were repeated. Fluid absorption artefacts were within +/-1 per cent of wear magnitude for PTFE and +/-8 per cent for polyethylene and were corrected f Wear rates were linear as a function of test duration. Precision within each se of three cups was within +/-6 per cent. The wear rates from experiments repeated over 15 months were reproducible to within +/-24 per cent. Howeve the magnitudes of the simulator wear rates were not clinically accurate, the PTFE wear rates (2843 mm3/10(6) cycles; 22 mm diameter) were over three times higher than in vivo, the polyethylene 30 to 50 per cent on the low side mm3/10(6) cycles; 22 mm diameter). Volumetric wear rate increased with respect to size of femoral head and a linearly increasing relationship of 7 8 p cent/mm was evident with respect to femoral head diameter for both PTFE a polyethylene. These data compared well with the clinical data.

PMID: 9141888 [PubMed - indexed for MEDLINE]

1: J Biomed Mater Res. 1997 Sep 15;36(4):529-35. Related Articles, L

Effect of femoral head diameter on tissue concentration of wear debris.

Hirakawa K, Bauer TW, Hashimoto Y, Stulberg BN, Wilde AH, Secic M

Department of Pathology, Cleveland Clinic Foundation, Ohio 44195, USA.

Although several studies have reported the physical properties of debris particles in tissues adjacent to failed total joint implants, few have correlated the results of particle analysis with other clinical and implant variables belie\ to influence implant wear. We retrospectively analyzed 41 fibrous membrane (from 35 patients) adjacent to failed acetabular cups from a single manufactu and studied the relationship between three different femoral head sizes (26, 2 and 32 mm) and the characteristics of wear debris in the adjacent tissues. All total hip prostheses consisted of modular cobalt-chromium alloy femoral hea articulating with titanium-alloy-backed ultrahigh molecular weight polyethylene (UHMWPE) acetabular components from a single manufacture Large femoral head diameter (32 mm) was found to correlate significantly w large particle size (diameter and surface area, $p < 0.05$), high tissue concentration of particles (particle volume/gram of tissue, $p < 0.01$), and higl rate of particle production (particles volume/month, $p < 0.05$). The results of these quantitative assays support the findings of radiographically based clinic studies that show higher volumetric wear associated with 32 mm femoral hea components.

Publication Types:
- Clinical Trial

PMID: 9294769 [PubMed - indexed for MEDLINE]

John Charnley

Low Friction Arthroplasty of the Hip

Theory and Practice

With 440 Figures, 205 in Colour

Springer-Verlag Berlin Heidelberg New York 1979

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Chapter 1

Low Friction Principle

The term low friction arthroplasty (or more correctly low frictional torque arthroplasty) was coined to emphasize the small diameter of the prosthetic head (22 mm) essential to the underlying theory. Low friction arthroplasty (LFA) is characterised even more particularly by the combination of a small prosthetic femoral head with a socket of maximum external diameter. Consequently the socket has maximum wall thickness.

The theory of low frictional torque arthroplasty is summarized in Fig. 1.1 reproduced from the Lancet 1961 under the title 'Arthroplasty of the hip—a new operation'. [1]

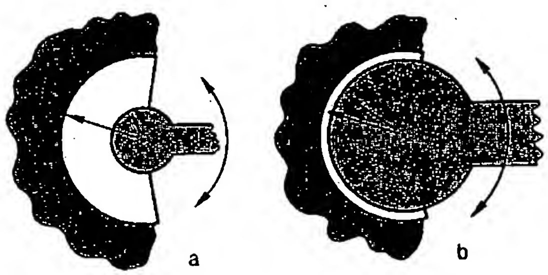

Fig. 1.1 a, b. Original illustration of the low friction torque principle applied to hip arthroplasty. a Thick socket-small femoral head: difference in radii favours socket remaining stationary; b not so with only slight difference in radii

Lubrication of Animal and Artificial Joints

The author's approach to total hip replacement from the point of view of lubrication started as a result of a chance encounter with a patient who had a Judet femoral head replacement for osteoarthrosis 1 or 2 years previously and whose hip in certain positions emitted an audible squeak. Enquiries established that colleagues had also had similar experiences. In the X-rays the stem of the prosthesis was seen to be lying in a grossly enlarged track in the femur, and this suggested that under load high friction between the head and the arthrosic socket was resisting movement and that the movement was now taking place between the loose stem and the femur.

This incident served to emphasize the ignorance of basic principles of lubrication, as applied to artificial animal joints, which existed at that time. The mere fact that a polished sphere of a plastics material, or of metal, felt 'slippery' when wetted with tissue fluids and handled in surgical rubber gloves, was no proof that this slippery behaviour would persist in an arthrosic acetabulum under heavy loads.

Lubrication of Animal Joints

At that time the universally accepted theory of lubrication in animal joints gave a dominant role to the action of synovial fluid. Maconnaill (1950)[2] was impressed by the incongruity existing between joint surfaces in the range of movement used when moving under load, compared with what he called the 'close-packed' situation adopted by some joints, as part of a muscle-sparing mechanism, when 'standing at ease'. Maconnaill saw in the incongruity of joint surfaces Nature adopting the principle of hydrodynamic lubrication, demonstrated par excellence in the Michel bearing, where convergent wedges of fluid generate pressure under the action of rotation and separate the surfaces moving under load.

Applied to animal joints however this concept was not convincing, because slow motion, and especially slow oscillating motion, is not ideally suited to the persistence of full-thickness fluid films between sliding surfaces.

Up to that time the only experimental work which had been published on the lubrication of animal joints was that of E. Shirley Jones (1936)[3], and of a number of experiments the one of greatest interest was that in which he made a freshly amputated human finger joint function as the pivot of a pendulum. This was an elegant experiment because it explored the resistance to movement of a loaded joint with the surfaces sliding at different speeds. This is because of the well-known fact of a pendulum that the time for each swing is the same whether the amplitude be large or small; therefore at the start of the experiment the speed of sliding will be high when the amplitude is great and will get progressively less as the amplitude decays. In his experiments with the amputated finger joint Jones found that when plotted against time the decrement of each swing behaved in an exponential fashion, which meant that frictional resistance was disproportionately high at high speeds of sliding. This was consistent with the viscous behaviour of a fluid and from this it was concluded that lubrication of the finger joint must incorporate a hydrodynamic mechanism (Fig. 1.2).

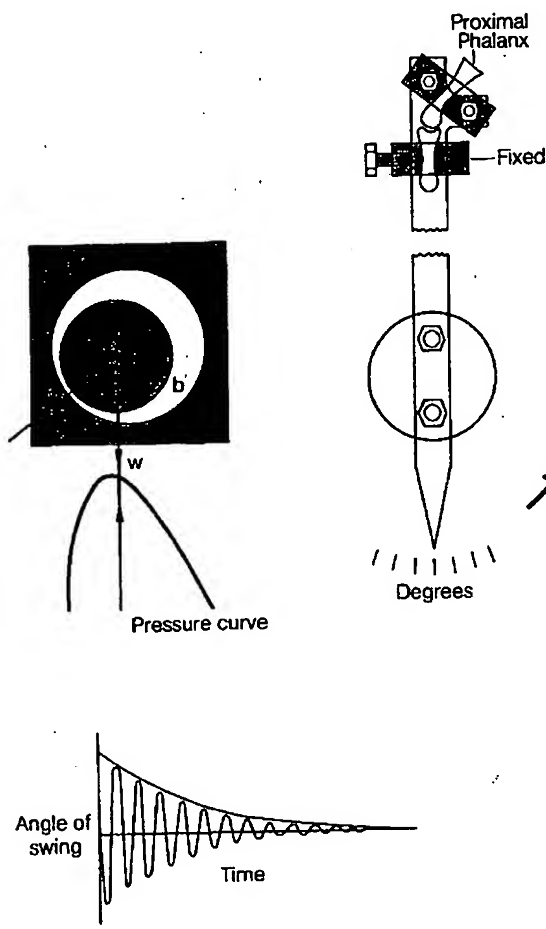

Fig. 1.2. Original experiment of E. Shirley Jones reproduced from his paper

The regime of lubrication which is the diametric opposite of hydrodynamic lubrication is known as 'boundary' lubrication. This mode of lubrication is equivalent to the sliding of dry surfaces which possess intrinsically slippery qualities; the extreme examples being graphite or molybdenum sulphide or polytetrafluorethylene. Also in this category is the lubricating action of substances which react chemically with the sliding surfaces and thereafter function as molecular films too thin to show viscosity in accordance with the laws of fluid mechanics. A good example of this is the lubricating action of fatty acids such as the oleic, stearic, palmitic acids, etc., which form soaps in combination with the metal surfaces of plain bearings. The intriguing feature of this mode of lubrication is that though extremely thin, as a result of being bound chemically to the sliding surfaces, the lubricating films are more resistant to rupture than thick films of grease or oil unable to make a chemical bond with the sliding surfaces. In these latter cases a film of oil or grease would be able to remain intact only as a result of the (relatively small) molecular forces acting between the molecules of the oil itself.

The boundary mode of lubrication seemed to the author ideally suited to the lubrication of slow-moving, heavily loaded animal joints and especially since these were exposed to oscillating motion and capable of remaining stationary under load for several seconds without exhibiting 'stiction' at the moment of resuming movement. It seemed possible that Jones had made an error in choosing a finger joint for the pivot of his pendulum because a finger joint is unstable in the absence of the collateral ligaments and to retain the ligaments would offer greater resistance at large amplitudes of swing than at small ones; this could explain an exponential pattern of decay of amplitude without postulating a viscous fluid mechanism.

The author repeated the pendulum experiment, this time choosing a human ankle joint (Fig. 1.3).

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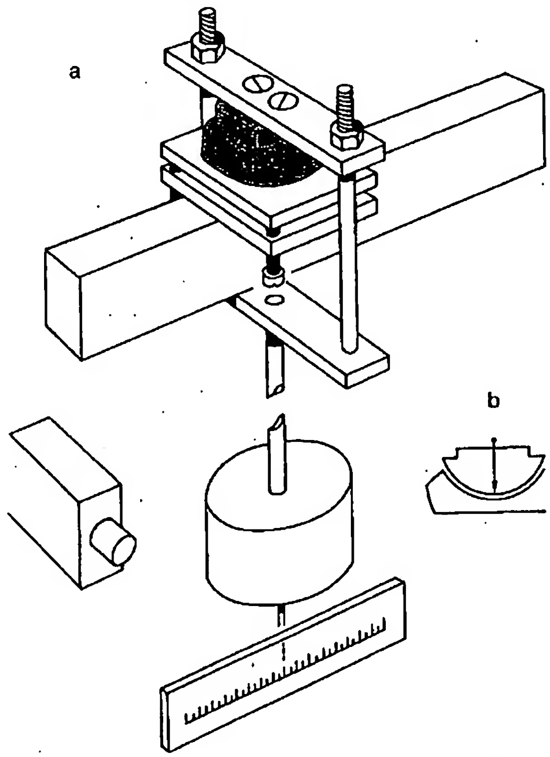

Fig. 1.3. Pendulum experiment using human ankle-joint

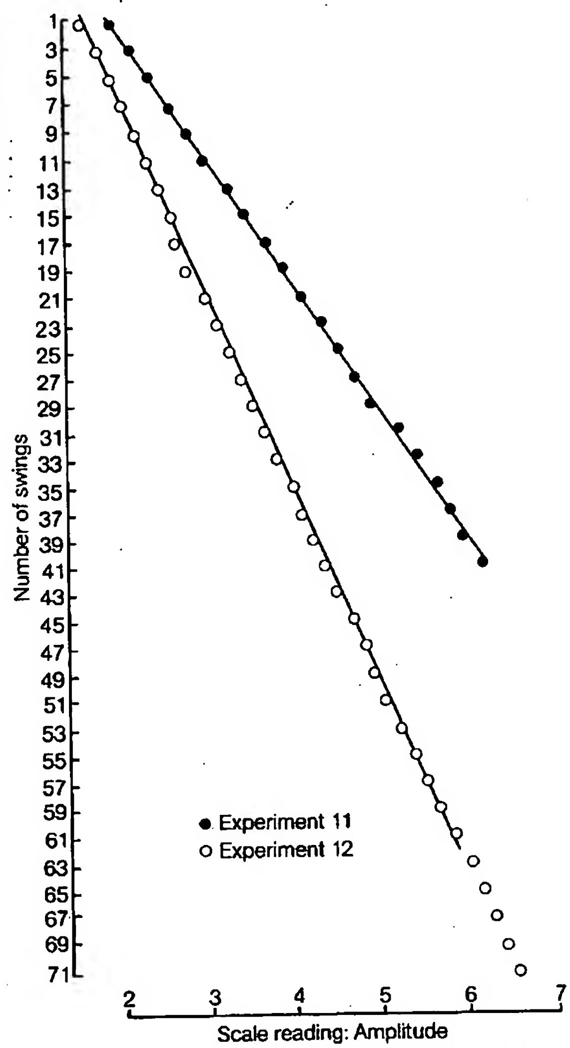

Fig. 1.4. Graphs of decay of amplitude with number of swings. Increase in number of swings when visible synovial fluid was not wiped away with dry cloth (Expt. 12 compared with Expt. 11) did not change straight line performance

Because of the deep curvature of the components of the ankle joint this biological pivot was self-locating in the absence of collateral ligaments. In these experiments the decay of amplitude followed a straight line (Fig. 1.4) indicating that the coefficient of friction in the joint remained the same despite changes in the rate of sliding. This is a recognised feature of boundary friction within certain fairly wide limits of speed. It was interesting also to note that the straight-line behaviour of the decrement of amplitude was not greatly changed whether the ankle joint was visibly wetted with synovial fluid or had been wiped clean of visible liquid with a dry cloth. This suggested that a smear of lubricant was as effective as a large volume, a state of affairs more in accordance with the theory of boundary lubrication than hydrodynamic lubrication.

Against the theory of boundary lubrication as the sole explanation of lubrication in animal joints is often advanced the fact that the coefficient of friction of an animal joint is so astonishingly low (in the region of 0.01 or even less) and in ordinary engineering practice most examples of boundary lubrication have coefficients of friction in the region of 0.10 or higher.

However, it is still possible that the last word has not yet been said on the ultimate nature of lubrication in animal joints and, as is commonly the case in matters of lubrication, a mixed regime of fluid film and boundary lubrication probably exists, with Nature having discovered a unique means of making a mixed regime.

Synovial Fluid as a Lubricant

In the designing of a total joint replacement the practical importance of the foregoing remarks is that when these experiments were extended to the substances likely to be used in the construction of artificial joints [before the introduction of high molecular weight polyethylene (HMWP)] it was found that synovial fluid was incapable of acting as a lubricant. Thus a chrome-cobalt surface sliding on chrome-cobalt; stainless steel sliding on bare bone; and Perspex (Lucite or polymethylmethacrylate) sliding on bare bone; when lubricated with bovine synovial fluid all presented coefficients of friction in the region of 0.5 and squeaked under load. On the other hand stainless steel sliding on normal articular cartilage was well lubricated with synovial fluid (coefficient of friction in region of 0.05) and this combination therefore was not greatly inferior to articular cartilage sliding on articular cartilage (Fig. 1.5).

These observations therefore seemed to indicate that synovial fluid was a specific lubricant for articular cartilage and for nothing else. The specificity of a lubricant for the material of a surface is characteristic of boundary lubrication because it involves that quality known as 'oiliness'. This does not apply in hydrodynamic lubrication where oiliness in a lubricant is unnecessary: water or air can be used to lubricate hydrodynamically, provided that the geometry of the rotating surfaces, the area of the surfaces, the load to be carried and the speed of rotation are all known.

From these considerations the author decided in 1958 that the only chance of success in lubricating an artificial animal joint would be by using surfaces which were intrinsically slippery on each other; in other words, self-lubricating irrespective of whether tissue fluid were present or not. This led to trials of polytetrafluorethylene (Teflon,

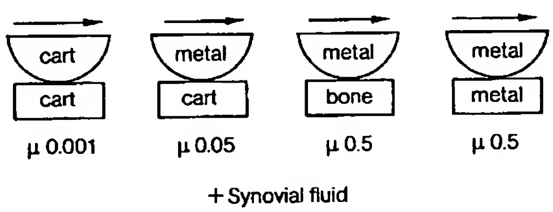

Fig. 1.5. Typical coefficients of friction with different pairs of substances in hip arthroplasty

PTFE), with spectacular early results. Unfortunately the poor wearing properties of pure PTFE, and the disastrous complications with PTFE 'filled' with material designed to enhance wear resistance, ended in PTFE being abandoned in 1961, after some 300 total hip operations had been performed with a number of different mechanical modifications. The PTFE era taught a number of very important lessons which might still have warnings for future development in this field and for this reason a brief review of selected experiences is cogent.

a) Particle Size and Tissue Reaction

It is now well known that PTFE in the hip joint produced voluminous masses of amorphous caseous material. This presumably is the proteinaceous material resulting from vast numbers of dead foreign-body giant cells. Particle size might be very important in the production of granulomatous material because PTFE particles were very large (often $300\ \mu m$) and their large size could prevent transport away from the site of production. The high rate of production of PTFE particles (rapidity of wear) in addition to the large size of the particles, might have been responsible for defeating the available transport system for removing the particles and the caseous debris. Therefore slow production (high wear resistance) and small size of abraded particles might be important features in reducing local accumulations of caseous material even if the production of wear particles may never be avoided.

Therefore it would seem possible, if wear has to be accepted as inevitable, that the ideal implant will produce very small particles. The factors which control the size of abraded particles of HMWP as yet are unknown but the particles produced in the (LFA) hip in the author's experience seem to be smaller than those produced in knee arthroplasties. This might suggest that the high loading of a small-diameter ball can prevent 'third body' abrasion, perhaps by burnishing the particles into the surface, perhaps by the tendency of the small-diameter head to 'bore' into the plastic and remain close fitting, rather than combining elements of rolling and sliding encouraged by the large-diameter spherical surfaces of the knee.

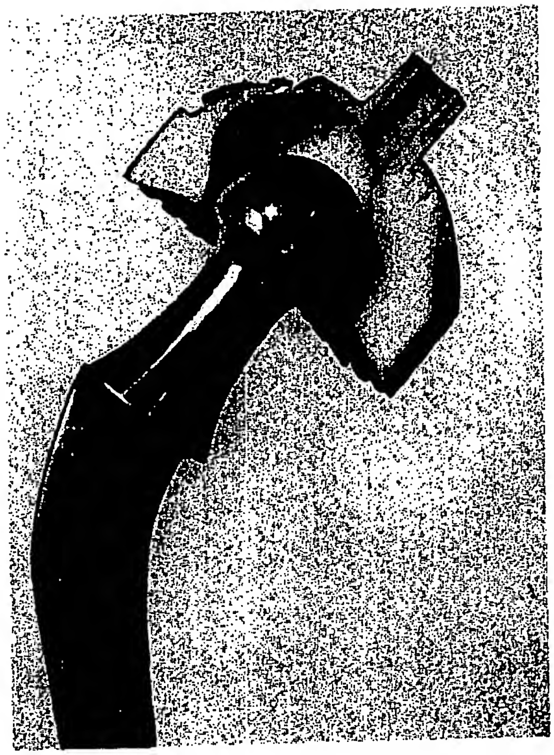

Fig. 1.6. Total wear-out of Teflon socket after 3 years. Note vertical direction of wear track

b) Direction of Socket Wear

The rapidity of wear of Teflon hip sockets enabled the direction of wear to be recognised in periods as short as 2 or 3 years (Fig. 1.6). When wear is very slight, as with HMWP, it is difficult to be sure of the precise direction of wear.

The frequency with which the direction of wear was vertically upwards, or even upwards and laterally, made Elson and Charnley (1968)[4] recommend that in designing total hip replacements we should not count on the joint force being advantageously inclined at 10° medially but we should assume that the joint force acts as though it were directed vertically. This emphasizes, among many other matters, the importance of designing the hip socket to be totally enclosed inside the acetabulum.

c) Fillers to Enhance Wear Resistance

PTFE filled with glass fibre, or with a synthetic proprietary substance (Fluorosint-Polypenco) showed enhanced wear ~~resistance~~ by a factor of 20 when lubricated with water in the laboratory. The surfaces of the plastics specimens also became highly polished in these laboratory experiments and the stainless steel counterface also remained in a high state of polish. In the human body however this type of filled PTFE behaved very badly. PTFE filled with glass fibre even after 1 year in the body developed a 'pasty' surface which could be scraped away with a blunt instrument. Fluorosint wore in the body just as rapidly as ordinary PTFE but the result was even worse, because the filler acted abrasively and lapped metal from the prosthetic head. The sockets retained a matt surface and never acquired the glazed surface that they did in the laboratory.

Ultra-High Molecular Weight Polyethylene

The introduction of HMWP by the author in 1962 as a material for socket surfaces in joint replacement necessitated a change of emphasis in lubrication theory as applied to artificial joints. The unique low coefficient of friction of PTFE could no longer be deployed and emphasis now had to be turned towards materials offering high resistance to wear and producing therefore a minimum of abraded detritus.

The coefficient of friction of HMWP is at least five times higher than that of PTFE, but its wear resistance in laboratory tests is 500–1000 times better. The very high wear resistance of HMWP now made acceptable the very high stresses on the plastics material produced by the small-diameter femoral head inseparable from concepts of low frictional torque. It thus became feasible to compensate for increased frictional resistance by designing for low frictional torque.

In this change of policy two unpredicted factors came to light which helped to offset the inferior coefficient of friction of HMWP compared with Teflon. In the first place HMWP is one of the plastics materials whose coefficient of friction becomes less under high stress; in the second place HMWP proved to be capable of a modest degree of boundary lubrication by synovial fluid. This latter property therefore made it an exception to

the author's statement in the early stages of this work that there were no substances available for joint replacement which could avail themselves of synovial fluid as a lubricant.

Pendulum Comparator

A method of attempting to compare the frictional torque of different designs of total hip implant is the pendulum 'comparator' illustrated in Fig. 1.7. This device, developed by the author at Wrightington, is not intended to measure absolute values of friction but merely to make broad, even qualitative, comparisons of the frictional torque offered by different designs of total hip replacement when compared against a 22-mm-diameter stainless steel sphere in a socket of HMWP. Like all methods of measuring frictional resistance these tests are prone to erratic behaviour and it is impossible to make fine distinctions over the middle range of observed results; but for its main purpose, which is to reveal extremes of behaviour, it is valid.

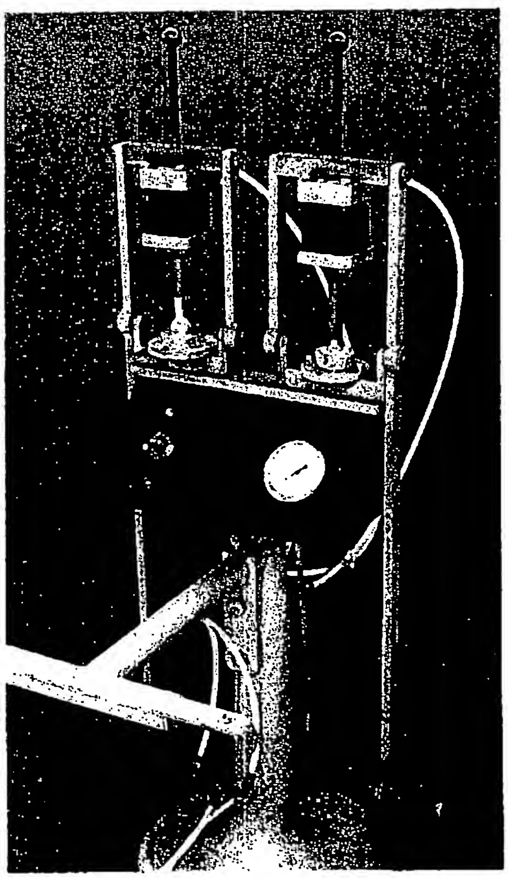

Fig. 1.7. Pendulum comparator

The device consists of two separate pendulum systems each with a heavy metal bob of identical weight and swinging on ball bearings. Each pendulum carries a cylinder and piston connected by a flexible tube to a compressed air source to deliver a force of about 200 lb (90 kg) at each piston rod. The femoral head component of the device to be tested must be cut from its stem and attached, by brazing, to a stub to fit the piston rod.

The sockets to be tested are mounted in metal holders using acrylic cement (Fig. 1.8). The point corresponding to the centre of the hemispherical cavity of the socket must be at a prescribed distance above the base plate on which the holder lies. This distance is the height of the horizontal axis passing through the ball bearings of the pendulum. The metal mounts taking the hip sockets locate on three pins on the base of the comparator.

The comparison is made by drawing both pendula to their maximum amplitude where they are held by a trigger. The bobs are released simultaneously without applying load to the hip implants to be compared. The number of swings is counted until the pendula start to be out of phase but of course are still swinging vigorously (this will usually be about 8-10 half-cycles). This demonstrates that in the unloaded state there is no gross difference between the two sides. The bobs are again brought back to the starting triggers and air pressure is applied to the two implants to be compared. The bobs are released and the number of half-cycles on each side are counted until each pendulum stops.

The tests are performed with bovine synovial fluid as a lubricant. It is important that the implants should be freshly washed in soapy water which is then eliminated by an adequate period under a running tap. Thereafter care should be taken not to get grease from the fingers on to the test surfaces.

The apparatus can be criticised as being unphysiological in that a constant load is maintained on the to and the fro half-cycles. It is not possible to design otherwise because slight errors of centring, inevitable when parts of the instrument deflect under the load, could produce serious errors if the load were applied repeatedly in one direction and removed in the other. By maintaining a constant load the errors caused by the load assisting the swing in one direction are neutralised by the load impeding the swing in the other direction.

Another criticism is that the state of any fluid film which might exist must be best at the start and that any contribution of fluid lubrication must decline throughout a test. Against this it is main-

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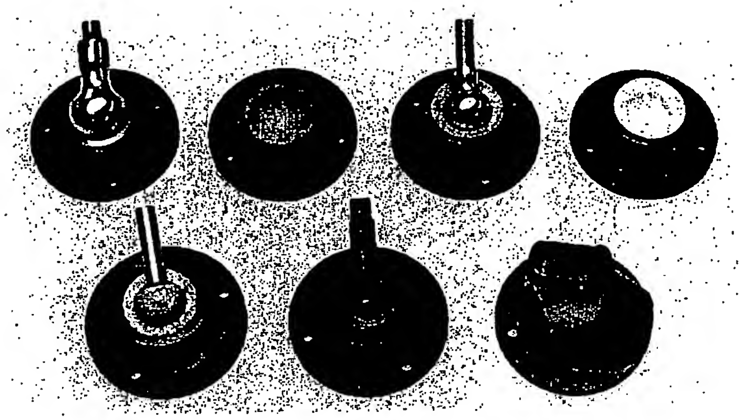


Fig. 1.8. Sockets mounted in holders to locate centre of rotation as near as possible to axis of the pendulum comparator.

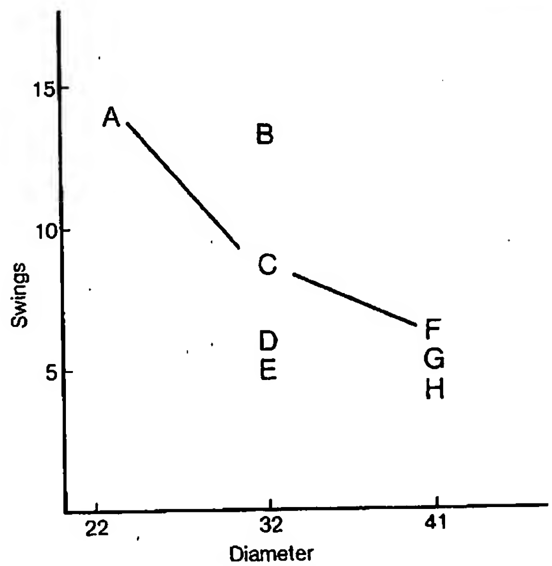


Fig. 1.9. *A, C, F,* represent different diameters of metal (stainless steel) ball on HMWP. The number of swings to stopping decreases as diameter increases: the opposite of what would be expected with fluid lubrication. Load 250 lb in all cases
D, polyester socket with 32-mm diameter chrome-cobalt head
E, ceramic (Al_3O_3) head 31-mm diamter on socket of same ceramic (Boutin)
B, ceramic (Biolox) head on HWMP socket
G, trunnion design (Weber) 42-mm polyester sphere
H, McKee–Farrar 41-mm chrome-cobalt head on socket of same

tained that, whatever may be the mechanism of lubrication, the comparison starts with all the joints being offered the same circumstances and the test reveals how different artificial joints react under these same starting conditions.

An important feature of the design is that the plane in which the ball oscillates is not unlike that during the weight-bearing phase of walking in the human body: the axis of rotation of the ball is at an angle to the central axis of the socket. To rotate the ball on the same axis as that of the socket would incur great variations in frictional torque depending on the fit of the ball in the socket: a large socket would give point contact with the head in the depth of the socket and therefore a very low frictional moment; a too-small socket would cause a 'cone-clutch' effect with binding of the head at the rim of the socket with very high frictional torque. An annular zone of contact halfway down the socket (as was recommended for the McKee-Farrar metal-to-metal implant) would give intermediate frictional torque. By oscillating in a plane perpendicular to the central axis of the socket, sensitivity to errors of fit of the ball in the socket is minimised because the length of the friction moment arm is the radius of the ball and is therefore constant.

Some typical results, the averages of many tests, all using lubrication with synovial fluid, are shown in Fig. 1.9. Points of special interest are as follows:

1. Metal/HMWP

The relationship between the number of swings and the diameter of the metal ball is well demonstrated in the sequence A (22 mm)—C (32 mm)—F (41 mm). If an important element of fluid-film lubrication were to be present one would expect that spheres with large diameters would make more swings than those with small diameters under

the same load because large-diameter spheres would generate lower fluid pressures than small spheres and large-diameter sockets would present a longer distance through which a viscous fluid would have to extrude under low pressures.

In practical tests the opposite is the case. The number of swings becomes fewer as the diameter increases (14 swings falling to 7 as the diameter increases from 22 mm to 41 mm) which is in favour of boundary lubrication theory.

2. Metal 32 mm/HMWP (C) compared with metal 32 mm/polyester (D)

The inferior performance of the polyester socket could be explained in several ways: (a) on boundary theory as indicating that the friction between metal and polyester was greater than with HMWP or (b) again on boundary theory that very thin (boundary) films of synovial fluid are not encouraged by polyester but are by HMWP. On hydrodynamic theory the inferior performance might be explained by the greater hardness of the polyester causing any fluid film that might be present to be immediately ruptured, whereas the compliance of the HMWP socket could permit a fluid film to spread and so reach a thinner layer before finally rupturing (elasto-hydrodynamic lubrication).

These explanations also apply to the behaviour of metal-to-metal prostheses (41-mm McKee chrome-cobalt) where three or four swings when dry is not improved at all (or only marginally) by adding synovial fluid.

3. Ceramic Spheres and Ceramic Socket [31-mm diameter (E) Boutin]

When first tested this combination performed well, being equal to a 35-mm metal sphere on HMWP i.e. C (7 swings). At this time the sphere and the socket both had a matt surface finish. After about 30 demonstrations in the pendulum comparator (perhaps 200 swings) the performance deteriorated to the present state (E) of only 4 swings. But worse than this, it now emits a high-pitched audible squeak. The appearance of the squeak and the deterioration of performance coincided with the rubbing surfaces acquiring some degree of polish.

4. Ceramic Sphere and HMWP Socket [(B) 30-mm diameter Biolox (Muller)]

This combination performs better than any other in the range equalling the performance of the 22-mm metal head. Because the Biolox head is 30 mm in diameter compared with the 22-mm metal head the coefficient of friction between this ceramic and HMWP must be less than that between metal and HMWP (The 30-mm Biolox head was an experimental head—the one used clinically is 32 mm in diameter.)

5. Trunnion Hip. Polyester sphere (42-mm diameter (G) Weber)

This unit performs badly in the pendulum comparator and is only slightly better than the 41-mm metal-to-metal McKee. It appears that very high frictional resistance between the large-diameter polyester sphere and metal socket prevents the small-diameter trunnion revealing its potential. It would seem that for a better performance the axis of the trunnion would have to be more horizontal if it is to share more of the flexion range of the hip joint.

Coefficients of Friction in the Literature

The precise value of the coefficient of friction between any two sliding substances depends very much on the method used to make the measurement; for this reason the literature contains different values for the various combinations of materials which have been used in artificial joints.

An interesting feature of the pendulum comparator is how the performance has changed when giving monthly demonstrations with the same specimens over the years, though the relative values have been fairly constant. This would suggest that changes, possibly oxidative, can affect the rubbing surfaces over 10 years. When polished again the original values were restored.

Generally speaking a coefficient of friction between 0.05 and 0.10 would appear to the accepted value for metal on HMWP lubricated with synovial fluid (Simon and Radin) [5]. Compared with

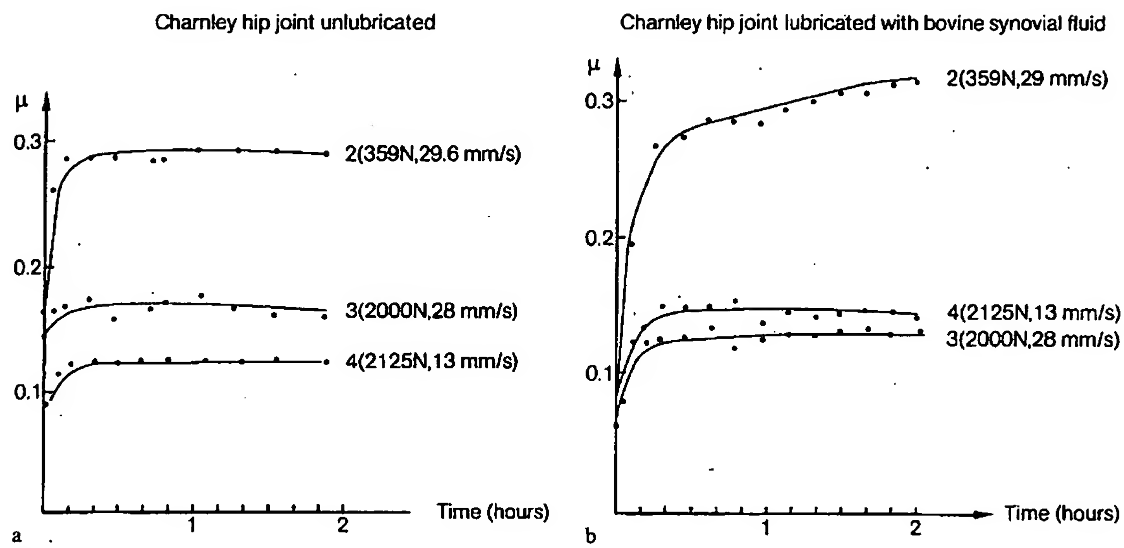


Fig. 1.10a, b. Leeds pendulum experiment with load varied throughout each cycle, by hydraulic mechanism, to simulate human gait. a Lubricated with bovine synovial fluid and b unlubricated. Note decrease in coefficient of friction as load increases. Fact that performance is not different, lubricated or not lubricated with synovial fluid, despite loaded and unloaded half-cycles, strongly favours boundary lubrication mechanism as major contribution to lubrication

the coefficient of friction in normal animal joints, an order of magnitude lower, these are not particularly low values.

In a series of experiments carried out by the Bioengineering Group in Leeds [6], using a different type of test, even higher frictional resistance was recorded with the 22-mm Charnley prosthesis on HMWP and the results were not materially reduced when lubricated with synovial fluid. This test was a pendulum experiment but the amplitude was maintained by an external power source. The load on the joint was varied by a hydraulically operated system which applied peak loads at the extremes of motion corresponding to 'heel-strike' and 'toe-off' in human gait. This physiological method of loading therefore would encourage fluid lubrication in the non-weight-bearing half-cycle, not possible in the author's very simple comparator. The frictional resistance was monitored at each swing. Fig. 1.10a, b reproduce their findings. It will be seen that within 10 min of starting a test, with or without synovial fluid, there was a rise in frictional resistance to 0.15 under a load of about 450 lb (2000 N). In this pendulum experiment it was notable that the coefficient of friction of the 22-mm head on HMWP, with or without synovial fluid, was less under high loads than when lightly loaded. Thus under 80 lb (359 N) $\mu=0.3$ whereas at 450 lb approx. (2000 N) the coefficient of friction was half this value ($\mu=0.15$).

Is Low Frictional Torque Essential?

High frictional torque in a total hip under the full load of joint force in theory will help to loosen cement bonds. In theory also high frictional torque will reduce the amount of external work which the muscles can do by energy lost as heat in the bearing. Energy lost cannot be demonstrated in clinical practice, though in metal-to-metal bearings in laboratory conditions it can always be demonstrated that they offer frictional resistance to movement under heavy load and become warm.

On four or five occasions the author has performed bilateral total hip replacement comparing the 22-mm metal-to-plastic LFA in one hip with a 41-mm-diameter metal-to-metal McKee in the other and, with technically sound implants on both sides, no subjective difference between the two sides was volunteered by the patient nor was admitted on questioning. These patients did not

notice any feeling of weakness on the side of the metal-to-metal hip when ascending stairs compared with their sensations on the low-friction side.

The author suggests as one possible explanation that in the load-bearing phase of ascending stairs the metal-to-metal bearing might 'lock' and function as an arthrodesis. The same theory could conceivably apply even in bilateral metal-to-metal arthroplasties when ascending stairs: in this case the unloaded metal-to-metal hip will flex freely to reach the upper step, then it will progressively lock as load is transferred to it; the locked opposite hip which is taking load then progressively unlocks as load is removed. A considerable experience of arthrodesis of the hip indicates that in a unilateral arthrodesis the only defective phase in mounting stairs is that of reaching the upper step with the foot of the arthrodesed side. The act of putting weight on the arthrodesed hip and raising the body offers no problem and the sensation is indistinguishable from that of normal hip. In offering this explanation the locking is visualised as a gradual process, the change from free movement to seizure occupying perhaps 10°. Another 10° could easily be contributed by movement of pelvis and spine.

Another curious phenomenon, in the light of bad performance in the laboratory, when considering the behaviour of metal-to-metal total hip joints in clinical practice is that patients do not feel 'stick-slip' (which is the basis of a squeak) yet this is invariably detected when attempting to move a metal-to-metal total hip lubricated with synovial fluid under heavy load in the laboratory. In an experiment which the author has demonstrated many hundreds of times to visitors, a 41-mm McKee arthroplasty is wetted liberally with bovine synovial fluid and while the visitor is moving it slowly to and fro, manually through the medium of a lever, air pressure is suddenly applied to deliver 200 lb force. The metal-to-metal total hip locks instantaneously without a detectable period even as short as 0.5 s which might be occupied by the extrusion of the synovial fluid. Thereafter to move the metal-to-metal joint demands very considerable force, a grinding sound is audible and vibrations are detected through the lever.

One explanation could be that patients might not have a sensory mechanism in the bones of the hip capable of transmitting this type of vibration to consciousness. It is always surprising to observe how patients with unoperated arthrosic hips which emit loud grating sounds seem to detect this by their ears just as do others in the same room; they do not seem to associate it with a special sensation coinciding with the grating sound.

Yet another explanation might be that in the living body, metal-to-metal joints might be lubricated with a type of synovial fluid which cannot be imitated by bovine synovial fluid in the laboratory. In other words, a proteinaceous substance in the living environment might become conjugated with the metallic elements in the sliding surfaces in a way not reproducible in the non-living circumstances of the laboratory.

As regards the question whether low frictional torque in a total hip replacement plays a significant role in preventing loosening of the cemented components, an argument cited against this is derived from experimental work on sockets cemented into the cadaveric acetabulum (Anderson et al) [7]. In this study it was found that torsional moments needed to loosen cemented sockets were from 4 to more than 20 times greater than any frictional moment capable of being transmitted from a prosthetic femoral head. While there can be no disputing these laboratory findings this type of experiment overlooks the fact that if demarcation of a cemented socket from the adjacent cancellous bone is present (from the biological reaction of bone to microscopic movement of cement in contact with it over a period of years) the avoidance of high frictional torque might permit such a socket to function for many more years than would be the case if high frictional torque were present. The loading of a cemented socket in the relatively constant direction of the joint force is almost certainly the main cause of socket loosening; but add to this high frictional torque in the later stages of this process and then clinical failure is accelerated.

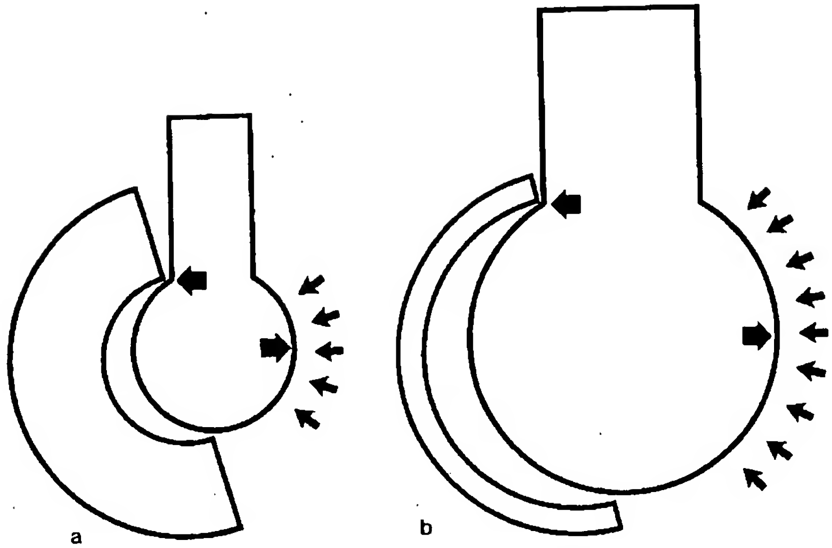


Fig. 1.11 a, b. Demonstrating magnitude of forces reacting on cement bonds, both of socket and of femoral prosthesis, at moment of traumatically exceeding designed range. **a** In case of small-diameter head, force resisting dilation of capsule is small; consequently equal and opposite force reacting against socket also is small; but thick-walled socket preserves maximum external surface area to resist shearing force imposed on it. **b** In case of large-diameter head, force resisting dilation of capsule is great; consequently equal and opposite force reacting against socket also is great; but external surface area of socket resisting shearing forces is identical with that in case **a**

Size of Femoral Head and the 'Safety Valve' of the Hip

The small-diameter femoral head demanded by the theory of low frictional torque originally caused some anxiety because obviously it could be prone to post-operative dislocation. Once the factors controlling stability had been clearly defined (Chap. 19) an advantageous side-effect was recognized in the possibility that transient subluxation could occur during severe trauma. By transient subluxation we mean momentary and incomplete escape of the femoral head from the socket when the joint is forcibly and traumatically made to exceed the designed range. Incomplete escape of the head is then followed instantaneously by return of the head to its normal position when the overstretched limb returns within its proper range.

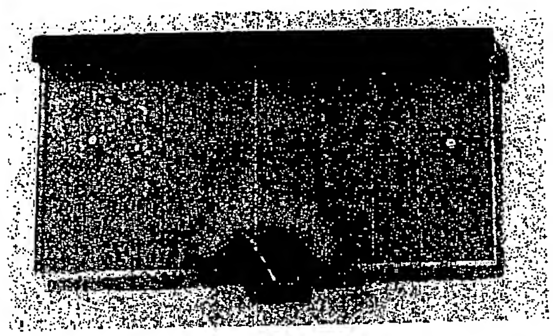
In the case of the 41-mm McKee prosthesis a common observation at secondary interventions is a bright spot on the neck corresponding with a point of impingement on the rim of the socket. McKee himself frequently attributed loosening of one or other of the components to the patient sustaining trauma as the result of a fall. In our experience with the 22-mm head we cannot recall a single case where loosening of cement clearly followed trauma. On the contrary it is a common experience to have elderly patients reporting back to hospital after falls, proved by demonstrating cuts or bruises on their knees.

The author's explanation is that if a 41-mm-diameter McKee head is at the critical point of starting to be levered out of the socket, as the range is being forced beyond the point of impingement of the neck, the large head will have to stretch the capsule (or the fibrous reconstruction of the excised capsule) to produce a much greater volumetric distension of the capsule than would be the case with a small head (Fig. 1.11). The force needed to do this would react on the stem of the femoral prosthesis and possibly also on the socket.

Thickness of Socket Wall

The concept of low frictional torque in total hip replacement using a prosthetic head of minimum

diameter and a socket of maximum external diameter, was prompted originally by the idea that a major difference in diameters would render cement in the acetabulum unnecessary. It was also recognized that a plastics socket with a thick wall would diffuse the load from a small ball more evenly over the socket-cement-bone interface than would a large ball acting through a thin-walled socket. The more uniformly loaded is the cement layer in the acetabulum the less likely is it to produce 'high spots' on the cement-bone interface which might precipitate minute, localised movement between cement and bone eventually producing a histiocyte reaction and bone cavitation with the start of loosening (Chap. 4).



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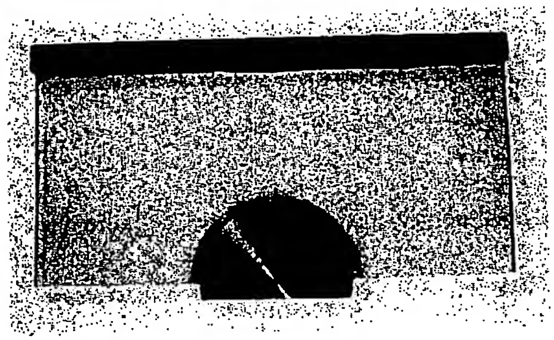

b

Fig. 1.12a, b. Photoelastic models to illustrate effect of thickness of socket on distribution of load. Sheet of photosensitive plastics material represents the bone of the acetabulum. It is important that the external surface of HMWP socket should be *adherent* to substance representing bone (simulating the socket-cement-bone entity). Grooved metal bar cemented to top of sheet of photoelastic material helps to diffuse load from test apparatus equally over the specimen, so reducing 'high spots' to a minimum.
a 22.25 mm diameter metal cylinder – 56 mm external diameter HMWP 'socket'; b 50 mm diameter metal cylinder – 56 mm external diameter HMWP 'socket'

With the general trend (by 1977) for designs of metal-to-plastics total hip to be moving towards the smaller ranges of femoral head (32, 28 and 25 mm) it seemed unlikely to be profitable to examine further the effects of small differences in diameter, but in 1978 the 'double-cup' design of hip arthroplasty has emerged, using a metal sphere up to 50 mm in external diameter with a socket only about 3 mm thick (Appendix B). Because the 14-year studies of the LFA (Chap. 6) have shown that socket loosening is going to be the most likely cause of very late failure, even with a small-diameter head and a thick socket, there is a possibility that a very large head and a very thin socket could be a retrograde step. This prompted the author with engineering colleagues[1]) to undertake photo-elastic studies to illustrate load distribution at socket-cement-bone interfaces in relation to the thickness of the wall of a socket.

The photo-elastic demonstration used two models where the bone of the pelvis was represented by a sheet of Araldite CT 200 and the metal spheres by cylindrical steel discs (Fig. 1.12). The large metal disc measured 50 mm in external diameter and the small disc, 22.25 mm. The HMWP sockets were represented by semicircular discs both 56 mm in external diameter cemented into semicircular concavities of the same diameter in the Araldite. It was imperative to have a cemented joint between the polyethylene and the Araldite just as in the living situation.

The concavities of the polyethylene discs originally corresponded to the diameters of the metal cylinders but after cementing in position were too tight, and scraping was necessary to achieve a fit which gave the same sensation of free movement present in the hemispherical specimens used in surgery.

When viewed through a circular polariscope the resulting fringe patterns for an applied load of 325 lb are given in Fig. 1.13 for the small ball and for the large ball. The fringe orders are proportional to the principal stress in the Araldite. For the small ball the maximum fringe order is estimated to be 2.5 and stresses are more or less evenly distributed over the 180° interface between the socket and the Araldite. For the large ball the maximum fringe order is estimated to be 3.5 and stresses are concentrated over the central 90° of the interface between the socket and the Araldite.

[1]) Dr. R. Kitching and Dr. R.D. McLeish, Department of Mechanical Engineering, University of Manchester Institute of Science and Technology.

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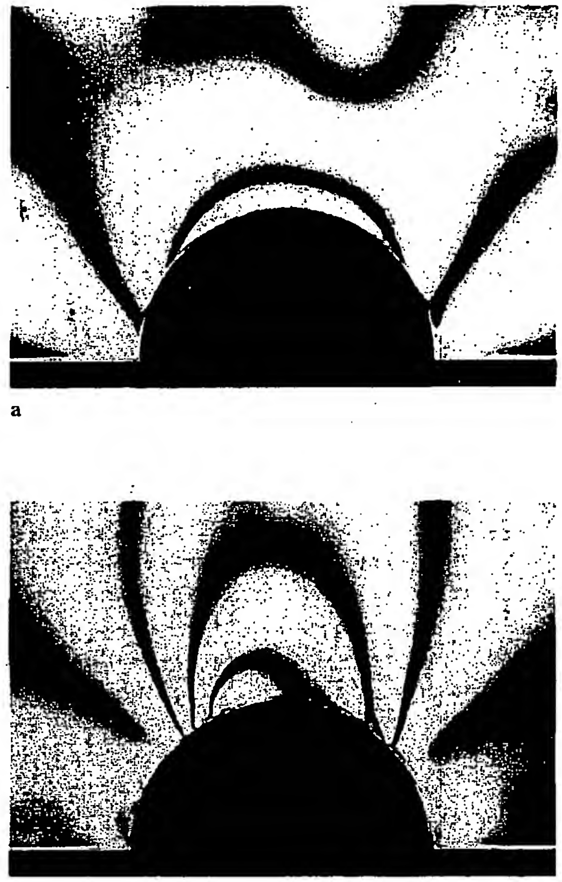
The maximum stresses in the plastic representing the bone of the acetabulum are (3.5/2.5) (1.4 times) higher with the thin socket than with the thick socket and these higher stresses are distributed over only about one-half of the area of cement-bone interface. The lower stresses produced by the thick socket are distributed more or less evenly over the whole area of the cement-bone interface. If the fit between the large ball and the thin socket were to be less good than in this experiment the zone of high stress would be more localised and higher in magnitude. With the thick socket on the other hand the stress will continue to be more evenly distributed on the cement-bone interfaces even if the ball were to be considerably smaller than a perfect fit.

From the point of view of the surgical manufacturer it is always difficult to be sure to what extent a socket of a plastics material made to close tolerances will hold these dimensions when internal stresses, etc. are relieved. It would be disastrous to use a socket which is too tight on a large head, because this could act as a powerful 'brake' and never have an opportunity to wear loose. Also to make different sockets and heads interchangeable, there will always be a tendency to deliver sockets erring on the side of looseness on a large head.

To this must also be added the fact that plastics materials have a much higher coefficient of thermal expansion than metal. Ideally a manufacturer should supply a socket which is too tight at room temperature so that it will be a perfect fit when at body temperature, but it is preferable to err on the side of a loose fit and hope that the head will adapt perfectly by a combination of wear and plastic flow.



a

b

Fig. 1.13 a, b. *Top illustration* shows the thick socket under load from small-diameter metal prosthetic head. Fringes are distributed evenly over whole surface of socket. *Bottom illustration* shows thin socket and large-diameter metal prosthetic head under same load as above. Stresses are now concentrated over only a 90° quadrant of socket surface and are nearly 1.5 × higher than in case above. Under polarised light and both under load of 325 lb: **a** Two fringes on specimen (a) of Fig. 1.12; **b** three fringes on specimen (b) of Fig. 1.12

1: J Bone Joint Surg Am. 1998 Aug;80(8):1175-85.

Fixation of acetabular cups without cement in total hip arthroplasty. A comparison of three different implant surfaces a a minimum duration of follow-up of five years.

Manley MT, Capello WN, D'Antonio JA, Edidin AA, Geesink RG.

Indiana University School of Medicine, Indianapolis 46202, USA. mtmanley@mindspring.com

We evaluated 377 patients (428 hips) who had been managed, by a total of fourteen surgeons at twelve clinical sites in the United States and Europe, wi a porous-coated press-fit acetabular cup, a hydroxyapatite-coated threaded screw-in cup, or one of two similar designs of hydroxyapatite-coated press-fi cups between April 1987 and November 1992. The same type of hydroxyapatite-coated femoral stem was inserted without cement in all patie After a minimum duration of follow-up of five years (mean, 7.9 years; range, 5.3 to 9.1 years), one (1 per cent) of the 131 hydroxyapatite-coated threaded cups, two (2 per cent) of the 109 porous-coated press-fit cups, and twenty-on (11 per cent) of the 188 hydroxyapatite-coated press-fit cups had been revise because of aseptic loosening. A common radiographic sign of impending fail of the hydroxyapatite-coated press-fit cups was radiolucency at the interface between the implant and the subchondral bone beneath it. This radiolucency usually was seen initially more than two years after implantation. Radiograp evaluation of the 383 acetabular implants that were in situ at the time of the most recent follow-up showed that 123 (99 per cent) of the 124 hydroxyapati coated threaded cups, 101 (98 per cent) of the 103 porous-coated cups, and 1 (89 per cent) of the 156 hydroxyapatite-coated press-fit cups were stable wit osseous ingrowth (as indicated by the absence of radiolucency at the interfac and the absence of migration within the acetabulum). The probability of revision due to aseptic loosening was significantly greater for the hydroxyapatite-coated press-fit cups than it was for the hydroxyapatite-coate threaded cups or the porous-coated press-fit cups ($p < 0.001$ for both comparisons). Within the group of patients who had a hydroxyapatite-coated press-fit cup, the probability of revision due to aseptic loosening was significantly greater in association with a young age ($p = 0.003$), female genc ($p = 0.02$), the use of a femoral head with a diameter of thirty-two millimeter

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1: Chir Organi Mov. 1997 Oct-Dec;82(4):393-9. Related Articles, L

Metal-UHWMPE (Ultra High Molecular Weight Polyethylene) wear: experimental testing.

[Article in English, Italian]

Affatato S, Terzi S, Nardi D, Toni A, Cianci R.

Laboratorio di Tecnologia dei Materiali, Istituti Ortopedici Rizzoli, Bologna.

Testing conducted on a hip joint simulator verified the Charnley hypothesis t the diameter of the prosthetic head is proportional to wear. The study was conducted by pairing heads in Ortinox TM with acetabular cups in polyethyl at high molecular weight (UHMWPE). A comparison between the different sizes of the heads (26 and 30 mm in diameter) showed a different trend in the wear rate; in particular, the head with a smaller diameter behaves better tribologically than the head with a larger diameter.

PMID: 9618977 [PubMed - indexed for MEDLINE]

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1: Clin Orthop. 1982 Jun;(166):284-91. Related Articles, L

Prosthetic hip range of motion and impingement. The effects of head and neck geometry.

Chandler DR, Glousman R, Hull D, McGuire PJ, Kim IS, Clarke IC, Sarmiento A.

Two major design parameters to total hip arthroplasty which can be selected optimize for anatomical variation are head diameter and neck length. By usin cadaveric pelvis mounted in a three-dimensional protractor, it was shown tha increased head-neck diameter ratio results in increased range of motion, with decreased prosthetic impingement, and that increased neck-length results in increased range of motion, with increased prosthetic impingement. Head diameter has no range of motion effect in arcs characterized exclusively by bony impingement, and neck length has no range of motion effect in arcs characterized exclusively by prosthetic impingement. The surgeon is currentl confronted with a variety of prostheses with different head-neck diameter rat and neck lengths. When choosing the optimal prosthesis for a particular patie the surgeon is often restricted by various anatomical constraints. While a larg head diameter cannot always be chosen, an adequate range of motion withou prosthetic impingement can still be achieved by ensuring that head-neck diameter ratio is optimum. A sufficient neck length to ensure adequate range motion is desirable, but the neck should not be so long that neck-socket impingement is of concern. Optimum clinical range of motion, with minimal prosthetic impingement, may be achieved with a large head size and a mediu neck length.

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THE ROLE OF ACETABULAR COMPONENT SCREW HOLES AND/OR SCREWS IN THE DEVELOPMENT OF PELVIC OSTEOLYSIS

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Introduction: Anecdotal reporting of osteolysis around cementless modular acetabular components with holes through the metal shell and/or iliac fixation screws has raised concerns that such designs may generate excessive particulate debris and/or permit direct access of particulate debris to iliac bone. Incidence data has not been reported for these scattered cases. To determine the incidence of pelvic osteolysis and the relationship to acetabular component design features, we reviewed radiographs of 513 total hip replacements. The acetabular components used in these reconstructions have different design features which include, one-piece versus modular construction, solid shells versus shells with holes, and fixation screws versus no screws.

Materials and Methods: Sequential radiographs were reviewed by the same investigator from six different single-surgeon THR series using porous ingrowth acetabular components (AC). The occurrence and location of non-linear, scalloped or cystic pelvic bone resorption (osteolysis) was recorded. <u>Group 1</u> was a solid, one-piece, beaded, cobalt-chrome AC stabilized by three screws placed through peripheral flanges. <u>Group 2</u> was a titanium fiber-mesh AC with a modular polyethylene liner and multiple screw holes through the shell stabilized 2-5 screws. <u>Group 3</u> was this same AC "press-fit" without any screws. <u>Group 4</u> was a solid, one-piece, porous coated cobalt-chrome AC stabilized by three spikes. <u>Group 5</u> was a modular titanium fiber-mesh AC with an intrinsically stable chamfered cylinder design (CCD). Thirty-five of these had a completely solid shell and 78 had a single 8.5mm pilot hole. <u>Group 6</u> was a dual-geometry component that had intrinsic stability and multiple screw holes.

Results: With follow-up ranging from 40 to 108 months, a total of forty-five pelvic osteolytic lesions were observed (8.8%). Pelvic osteolysis was seen nearly as frequently in the ischium and pubis (21 lesions) as it was in the ilium (24 lesions). Ischial and pubic osteolysis cannot be explained by holes and/or screws through the acetabular component shell. On this basis alone, an alternative explanation of pelvic osteolysis with cementless acetabular components is needed.

There was no direct correlation between the presence of screw holes or screws and the incidence of pelvic osteolysis. The incidence of pelvic osteolysis around modular components with holes through the shell was 4.5% (fourteen of 313 hips). The incidence of pelvic osteolysis with solid-shell components was 15.5% (thirty-one of 200). The incidence of pelvic osteolysis around acetabular reconstructions with screws was 2.3% (three of 133). The incidence of pelvic osteolysis in reconstructions without screws was 11.1% (thirty-two of 380). The incidence of pelvic osteolysis with modular components was 6.9% (twenty-four of 348) and the incidence of pelvic osteolysis in one-piece acetabular components (polyethylene pre-fixed in the metal shell) was 12.7% (twenty-one of 165). The development of osteolysis was associated with larger head sizes and/or longer follow-up.

	No.	F/U	Diam.	Cup	Screws	Pel. Ol	Il.	Isc.	Pub.
1.	50	85	26	solid	+	4%	1	0	1
2.	83	68	26	holes	+	1.2%	1	0	0
3.	122	56	28	holes	-	0	0	0	0
4.	115	90	32	solid	-	14%	12	2	5
5a.	35	74	SR*	solid	-	29%	6	2	2
5b.	78	59	SR*	hole	-	12%	3	6	2
6.	30	51	32	holes	-	6.7%	1	1	0

*SR = surface replacement; diam. 36-51mm

Discussion: If holes or screws through an acetabular component shell predisposed to pelvic osteolysis, then one would expect to have an increased incidence with such reconstructions. We have not observed this. Based on this review there does not appear to be a direct relationship between holes and/or screws through an acetabular component and the development of pelvic osteolysis. Further, ischial and pubic osteolysis cannot be explained by holes and/or screws through the AC shell. These data combined with intraoperative observations and tissue samples indicate that, regardless of other acetabular component design features, the major route of joint fluid and polyethylene wear debris to the bone behind the component is from the femoral-acetabular articulation around the periphery through regions of the implant-bone interface without sufficient contact or tissue ingrowth, similar to what has been demonstrated for cemented AC.

Improvements in joint implants are necessary to minimize the generation of particulate debris and access to bone. While screw holes may provide an access channel in specific cases, our data, if all other factors in this comparison were equal, would suggest that the simple elimination of holes through the acetabular shell will not eliminate pelvic osteolysis. The development of pelvic osteolysis is multifactorial and includes the total volumetric wear of polyethylene as well as <u>specific</u> features of the AC design and reconstruction technique.

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The Relationship between the Design, Position, and Articular Wear of Acetabular Components Inserted without Cement and the Development of Pelvic Osteolysis*

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Investigation performed at the Joint Replacement Institute, Los Angeles

5 year

ABSTRACT: Between 1983 and 1987, an acetabular component with a unique chamfered-cylinder design was inserted without cement in 134 hips. With use of this design, initial stability is achieved through a cylindrical interference fit with the peripheral rim of the acetabulum, without the need for pegs, spikes, or screws.

At an average of sixty-four months (range, forty to ninety-six months) after implantation, follow-up data were available for 113 hips (ninety-three patients). No component had been revised for loosening or was radiographically loose. However, the prevalence of balloon-like osteolysis of the pelvis was 17 per cent (nineteen hips). This bone loss was generally not associated with pain or other symptoms.

Ten of the nineteen hips that were associated with pelvic osteolysis (including six of the nine that were associated with osteolysis of the ilium) had been reconstructed with use of an acetabular component that had no holes in the shell (that is, the shell was completely solid). This finding indicates that, while elimination of holes through the acetabular shell may have advantages, it will not prevent pelvic osteolysis. The osteolysis of the ilium was associated with a lateral opening of the acetabular component of more than 50 degrees ($p < 0.0001$).

All of the hips in this series had insertion of a porous-ingrowth femoral resurfacing component made of titanium alloy. These components are no longer used. Revision of the femoral side due to osteolysis provided a unique opportunity to inspect directly forty-two clinically well functioning acetabular components. All of the polyethylene liners and acetabular shells were found to be rigidly fixed. Inflammatory tissue at the periphery of the implant-bone interface resulted in circumferential resorption of periacetabular bone despite rigid fixation of the component. This is direct evidence that a process of bone resorption similar to that reported at the cement-bone interface of cemented acetabular components can occur at the implant-bone interface of components inserted without cement. At the reoperation, a communication that had led to the pelvic osteolysis was found through areas of bone resorption at the periphery of the implant-bone interface. These areas were essentially cystic and were filled with a mixture of fluid and friable, yellow-tan tissue. It appeared that the osteolytic process had expanded into the soft cancellous bone and marrow while being contained by the denser cortical shell of the pelvic bones. Thus, even with an implant designed to achieve a tight peripheral fit, osteolysis of the pelvis occurred.

Although fixation of the acetabular component has been improved by porous-ingrowth technology, bone resorption remains a problem. Compared with the cement-bone acetabular interface, porous ingrowth may offer increased resistance to the ingress of joint fluid and wear debris into the implant-bone interface, but fluid and debris may seek other pathways away from the interface, including the soft cancellous bone of the pelvis.

Data from Wrightington Hospital in Manchester, England, and from other centers have indicated that the major long-term problem with total hip arthroplasty performed with cement is loosening of the acetabular component accompanied by loss of acetabular bone and migration of the component[30]. This problem has been linked directly to wear of the polyethylene acetabular component. Analysis of cemented acetabular components in specimens that have been retrieved at autopsy revealed that small polyethylene wear particles at the periphery of the cement-bone interface were associated with a foreign-body inflammatory response, which initiated loosening by progressive resorption of the bone immediately adjacent to the cement mantle[27].

A five to seven-year review of radiographs suggested that a similar process of interfacial bone resorption may occur with acetabular components inserted without cement[23], and the histological findings from the periphery of the implant-bone interface of these components were essentially identical to those of cemented acetabular implants[24]. The achievement of initial contact between the porous surface and the bone at the periphery of the acetabulum has been associated with a reduction in progressive radiolucencies at the periphery, possibly by retardation of the ingress of joint fluid and polyethylene

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TABLE I

DATA ON THE NINETEEN PATIENTS (NINETEEN HIPS) WHO HAD PELVIC OSTEOLYSIS

Case	Sex, Age (Yrs.)	Diagnosis	Side	Lat. Opening (Degrees)	Type of Version	Site of Lesion	Size of Osteolytic Area (cm)	Duration Postop. until Lesion First Seen (Mos.)	Duration until Reop. (Mos.)	Duration of Follow-up (Mos.)	Polyethyl. Wear (mm)	Hole in Acetab. Shell	Hip Score[4] (Po… Pain	Walk.	Func…
Group 1*															
1	M, 69	Osteoarth.	L	66	Antevers.	Ilium	5.5 × 7.5	10	48	85	6.5	No	10	7	6
2	M, 37	Osteoarth.	L	55	Retrovers.	Ilium	2.0 × 2.5	32	71	79	2.5	No	7	9	9
3	M, 61	Osteoarth.	R	62	Antevers.	Ilium	2.5 × 5.0	12	74	74	4.5	No	6	5	3
4	M, 58	Osteoarth.	L	50	Antevers.	Pubis	2.3 × 3.0	13	96	96	3.5	No	10	10	9
Average	56			58			3.1 × 4.5	17	72	84	4.3				
Group 2†															
5	M, 53	Osteoarth.	L	65	Antevers.	Ilium	1.0 × 1.5	19	19	81	6	Yes	8	8	7
6	M, 63	Osteoarth.	L	60	Neutral	Ilium	1.0 × 1.0	25	50	63	1.5	No	7	8	8
7	M, 37	Osteonec.	R	50	Antevers.	Ilium	3.0 × 5.0	41	66	67	1.5	Yes	8	10	10
8	M, 56	Osteoarth.	L	55	Neutral	Ilium, ischium	2.5 × 6.7, 2.2 × 2.3	12	54	60	0.5	Yes	8	10	8
9	F, 39	Osteoarth.	L	40	Neutral	Ischium, pubis	2.0 × 2.0, 0.5 × 1.5	33	77	78	1.5	Yes	9	9	8
10	F, 55	Fract.-disloc.	R	35	Antevers.	Pubis	2.0 × 2.1	18	66	70	0.5	Yes	6	6	9
Average	51			51			1.8 × 2.8	25	55	70	2				
Group 3‡															
11	F, 69	Osteoarth.	L	65	Antevers.	Ilium	1.2 × 1.2	15	—	79	2	No	9	10	8
12	M, 37	Osteoarth.	L	60	Neutral	Ilium	0.7 × 0.8	30	—	62	2	No	9	8	10
Average	53			63			1.0 × 1.0	23		71	2				
13	M, 30	Rheum. arthrit.	L	55	Neutral	Ischium	1.7 × 2.5	9	—	60	0.5	Yes	9	4	4
14	F, 59	Osteoarth.	R	55	Antevers.	Ischium	2.6 × 4.2	26	—	87	1	No	9	9	8
15	M, 67	Osteoarth.	L	35	Antevers.	Ischium	1.7 × 2.1	20	—	76	0.5	Yes	3	5	[illegible]
16	F, 70	Osteoarth.	R	45	Neutral	Ischium	1.5 × 1.5	28	—	60	0.5	Yes	9	10	8
17	F, 69	Osteoarth.	R	50	Neutral	Ischium	2.0 × 2.8	17	—	58	1.5	No	7	8	8
18	F, 65	Osteoarth.	R	44	Neutral	Ischium	3.0 × 3.0	36	—	47	1	Yes	10	9	6
Average	60			47			2.1 × 2.7	21		65	0.8				
19	M, 53	Osteoarth.	L	45	Antevers.	Pubis	1.4 × 2.0	38	—	88	0.5	No	10	8	10
Average, Group 3	58			51			1.8 × 2.2	24	—	69	1.1				
Average over-all	55			52			2.0 × 2.9	23		72	2.0				

*The patients in Group 1 had a revision because of mechanical failure of the acetabular component.
†The patients in Group 2 had a reoperation because of failure of the femoral resurfacing component.
‡The patients in Group 3 had well functioning hips.

a line drawn through the bottom of each teardrop contour. Medial migration was evaluated by measurement of the horizontal distance from a perpendicular line drawn through the base of the teardrop to the most inferior edge of the component. Wear of the polyethylene was estimated on the anteroposterior radiograph by measurement of the change of the center of the femoral component relative to the acetabular shell.

Although the relationship between a continuous radiolucency around an acetabular component inserted without cement and the mechanical stability of the component has not been determined[23], we analyzed the implant-bone interface for evidence of continuous radiolucency. We observed a pattern of bone loss in which resorption of periacetabular bone progressed away from the implant-bone interface and into the pelvic bones. In these instances, the bone resorption had a cystic and expansile nature (Figs. 1-B through 3-C, 4-A, and 4-B), which we refer to as balloon-like pelvic osteolysis. The measurements of these lesions were made on the anteroposterior radiographs.

At the reoperation, the stability of the polyethylene liner within the acetabular shell was assessed with use of vigorous manual forces in compression, distraction, and rotation. The stability of the acetabular shell was assessed by application of a vigorous compression load to the rim of the shell. If any motion was visible or if fluid was expressed from an interface, then the component was considered loose. The retrieved femoral components were inspected grossly for damage of the articular surface. Because the femoral side was revised to a conventional (stemmed) implant with a femoral head diameter of twenty-eight millimeters, the acetabular polyethylene liner, which had a large inner diameter, had to be removed and replaced with a polyethylene liner that had an inner diameter of twenty-eight millimeters. The retrieved polyethylene liners were examined grossly and with an optical microscope to assess both articular (concave surface) and backside (convex surface) wear patterns and embedded material.

At the reoperation, we routinely resected the entire pseudocapsule and any reactive soft tissue in the operative field. Histological analysis was performed on specimens of tissue from the pseudocapsule, soft tissue from the areas of bone resorption around the intra-articular margin of the acetabular shell, and tissue from any

gions of balloon-like osteolysis in the pelvis. Specimens were processed with use of standard techniques. The sections were examined under both plain and polarized light at a maximum magnification of 1000, with use of oil immersion and very high-quality optics (Zeiss-Photomicroscope IIIRS; Carl Zeiss, Thornwood, New York). A quarter-wave plate was used for bidirectional light polarization (model 1153; American Optical, Buffalo, New York). Ground sections of the porous surfaces were analyzed qualitatively for evidence of bone ingrowth.

Statistical comparisons of sample proportions were made with use of the Fisher exact test. Multivariate associations between the appearance of osteolysis and other variables, including the age and sex of the patients, the diagnosis, the hip-rating score[4], the size of the implant, and the position of the component, were made with use of logistical regression analysis.

Results

At the latest follow-up evaluation, or just before the reoperation for the hips that were revised (Table I), the average clinical scores (of a possible 10 points) for all 113 hips were 9 points for pain, 8 points for walking, 8 points for function, and 6 points for activity. The radiographic analysis revealed no evidence of migration or of other changes in the position of the acetabular component. No acetabular component had a continuous radiolucent line around it. Therefore, no acetabular component was radiographically loose.

Nineteen (17 per cent) of the 113 hips were associated with a balloon-like osteolysis involving the pelvis (Table I). The osteolysis was radiographically apparent as early as nine months postoperatively, and all of the lesions progressed over time. There were nine lesions in the ilium, eight in the ischium, and four in the pubis; one osteolytic lesion involved both the ilium and the ischium and another, both the ischium and the pubis. The average size of the lesion was 2.0 by 2.9 centimeters on the most recent anteroposterior radiograph. In ten of the nineteen hips, there was no hole through the shell of the acetabular component; that is, the shell was completely solid. Ten of the nineteen hips caused no pain or only slight pain. There was no significant difference between the clinical scores for the hips that were associated with pelvic osteolysis compared with those that were not.

The mean lateral opening of the acetabular component for all 113 hips was 48 degrees. The mean lateral opening for the nine hips associated with osteolysis of the ilium was 60 degrees (range, 50 to 66 degrees); for the eight hips associated with osteolysis of the ischium, 47 degrees (range, 35 to 55 degrees); and for the four hips associated with osteolysis of the pubis, 43 degrees (range, 35 to 50 degrees). Osteolysis of the ilium was

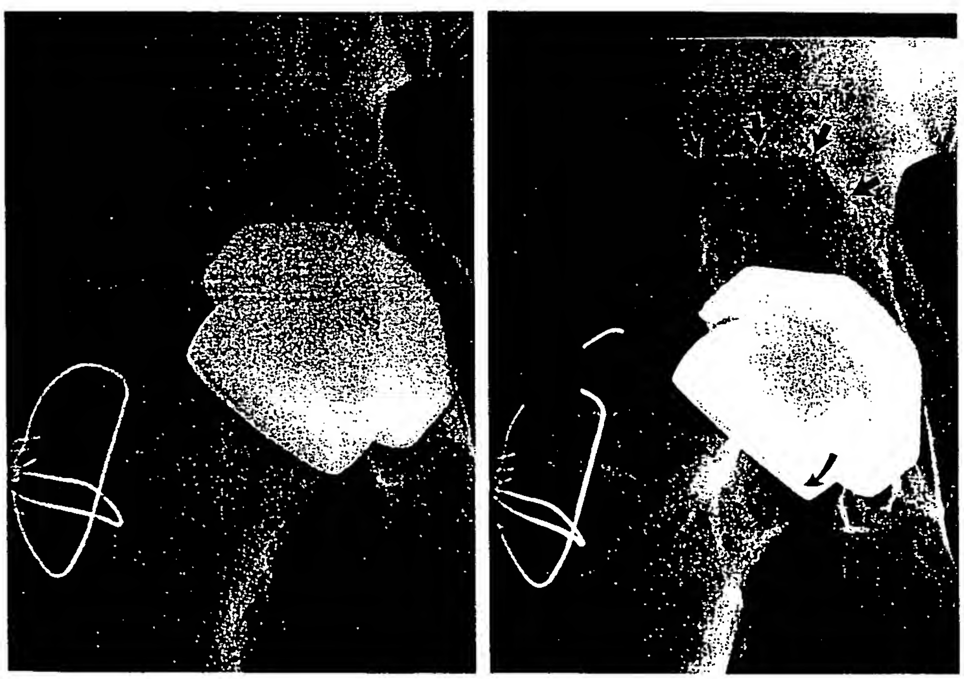

FIG. 2-A FIG. 2-B

Figs. 2-A and 2-B: Case 7.

Fig. 2-A: Early postoperative anteroposterior radiograph. The initial contact of the porous mesh with bone is excellent except for a small gap laterally. There is also an area of osteopenia directly superior to zone 2[9].

Fig. 2-B: Anteroposterior radiograph made before the revision. The patient had an elective conversion to a conventional (stemmed) femoral component because of the development of severe osteolysis of the femoral neck (curved arrow) and an impending fracture. The eccentric position of the femoral head within the acetabular component indicates substantial wear of the polyethylene, but the component is well fixed. Severe osteolysis also developed in the ilium (straight arrows). The osteolysis involves the lateral aspect (zone 1) of the acetabulum and includes the area of osteopenia in zone 2[9].

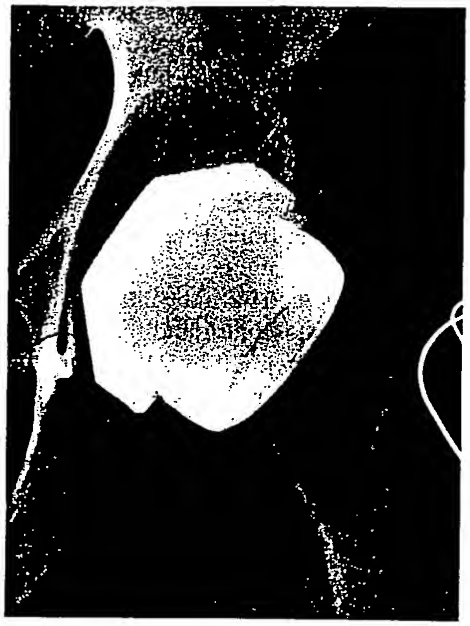

FIG. 3-A

Figs. 3-A through 3-D: Case 8.
Fig. 3-A: Early postoperative anteroposterior radiograph showing relatively low bone density medially.

associated with a lateral opening of more than 50 degrees ($p < 0.0001$). There was little risk of osteolysis of the ilium if the lateral opening was less than 50 degrees. For each 5-degree increase in the lateral opening of more than 50 degrees, to a maximum of 66 degrees, there was a four times greater risk of osteolysis of the ilium. Six of the nine hips that had osteolysis of the ilium had no hole in the shell of the acetabular component.

Four patients who had pelvic osteolysis had a revision of the acetabular component because of mechanical failure: three, because of a fracture of the titanium-alloy shell and one, because of debonding of the fiber-metal-mesh coating of the shell (Group 1, Table I). All four patients were men whose average age was fifty-six years (range, thirty-seven to sixty-nine years). The average time to revision was seventy-two months (range, forty-eight to ninety-six months). Osteolysis was present in the ilium in the three patients who had a fracture of the shell and a mean lateral opening of 61 degrees, and it was present in the pubis of the patient who had the debonded fiber-metal-mesh coating of the shell and a lateral opening of 50 degrees. All four hips had radiographic evidence of polyethylene wear; the combination of wear, lateral subluxation, and failure of the acetabular component resulted in an average superior migration of the femoral head of 4.3 millimeters (range, 2.5 to 6.5 millimeters). The radiographic estimation of polyethylene wear for all 113 hips was 1.4 millimeters, and it was 2.0 millimeters (range, 0.5 to 6.5 millimeters) for the nineteen hips that were associated with pelvic osteolysis. There was no measurable migration or other changes in the position of the shells of the four acetabular components that were revised. At the reoperation, the three intact components and the titanium fiber-metal mesh were found to be rigidly fixed.

Osteolysis progressed into an area of a large osteoarthrotic cyst in the ilium in one patient (Case 1), who had a lateral opening of 66 degrees (Figs. 1-A, 1-B, and 1-C). The cyst had been curetted and the site had been filled with bone graft at the time of the initial operation; however, osteolysis could be detected in this area ten months postoperatively. Because of the pre-existing

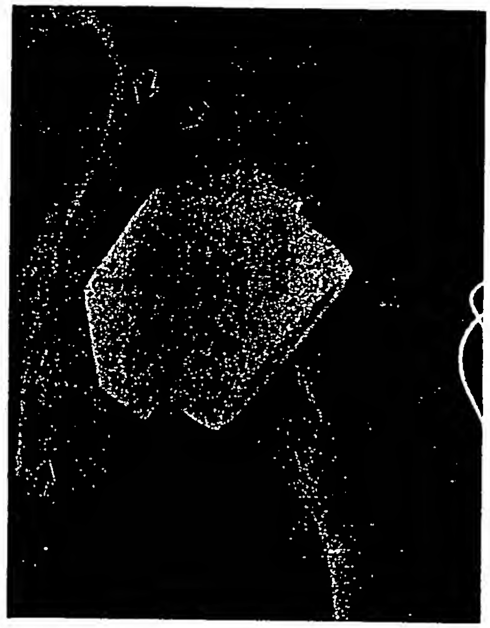

FIG. 3-B

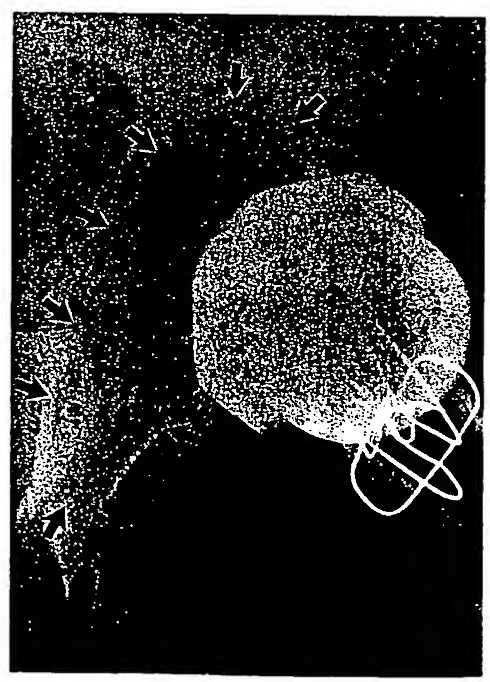

FIG. 3-C

Figs. 3-B and 3-C: Radiographs made before the revision. A cystic lesion (arrows) in the pelvis involves the low-density area.

cyst, the resultant area of bone loss was massive (5.5 by 7.5 centimeters), and it involved most of the iliac wing.

Forty-two of the 113 hips had a reoperation because of failure of the femoral resurfacing component. These hips were in twenty-nine male and thirteen female patients whose average age was fifty-two years. The average time to the reoperation was fifty months (range, seven to ninety-six months). None of the acetabular components in these patients were radiographically loose. Therefore, reoperation for these failures of the femoral side provided a unique opportunity to examine directly acetabular components that had been inserted without cement and were functioning well clinically. At the reoperation, the polyethylene liner was found to be well fixed in all forty-two hips; in fact, the stability of this liner made removal quite difficult. Sterile frozen saline solution was first placed into the component to cause shrinkage of the polyethylene. The rim of the polyethylene liner was marked for reference, and then Cobb elevators were used around the rim to pry the liner free from the shell. Considerable force was required. The instruments were inserted only around the rim, and care was taken not to damage the articular (concave) and the backside (convex) surfaces. In these forty-two hips, the shell of the acetabular component was also found to be well fixed.

Of the forty-two patients, six (four men and two women) had balloon-like osteolysis of the pelvis (Group 2, Table I). The average age of these patients was fifty-one years (range, thirty-five to sixty-five years). The average time to the reoperation due to failure of the femoral side was fifty-five months (range, nineteen to seventy-seven months). One patient (Case 7), who had a lateral opening of the acetabular component of 50 degrees, had massive osteolysis (three by five centimeters) of the ilium (Figs. 2-A and 2-B). At the reoperation, there was a tense joint effusion. Similar to the findings at the other reoperations, the joint fluid was mixed with a friable, yellow-tan material exuded from the periphery of the implant-bone interface. In several areas of the periphery of the interface, defects communicated with the pelvic osteolysis. The osteolysis appeared to be contained within the cortical tables of the pelvic bones, and it had expanded into the soft cancellous bone and marrow of the pelvis. Although not readily apparent on the radiographs, osteolysis of the ischium and the pubis was also found at the reoperation. Despite the extensive bone resorption, the component was rigidly fixed. Operative débridement of the osteolytic lesions was performed by working through the defects in the implant-bone interface. The friable, yellow-tan material was irrigated and curetted out of the lesions. A combination of autogenous graft and allograft was packed into the defects.

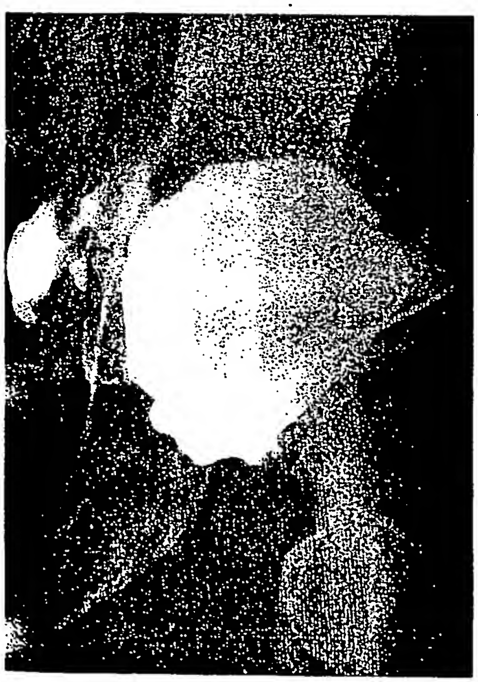

FIG. 3-D

Arthrogram, made at the reoperation, revealing a free communication of joint fluid with the cyst.

Another patient (Case 8), who had a lateral opening of the acetabular component of 55 degrees, had osteolysis of the ilium and the ischium that measured 2.5 by 6.7 centimeters and 2.2 by 2.3 centimeters, respectively (Figs. 3-A through 3-D). An arthrogram demonstrated contrast material in the area of the osteolysis. At the reoperation, a joint effusion was present. A defect in the posterior implant-bone interface led down into the ischium and also extended medially to a large cyst behind the acetabular component. The cystic cavities contained fluid and the same friable, yellow-tan material described previously. Despite the extensive resorption of bone, the shell of the acetabular component was well fixed. The osteolytic cavity was curetted and packed with autogenous graft and allograft.

One patient (Case 10), who had a lateral opening of only 35 degrees, had osteolysis of the pubis that measured 2.0 by 2.1 centimeters. This resulted in a fracture of the superior pubic ramus (Figs. 4-A and 4-B). At the reoperation, the osteolysis was found to communicate directly with the intracapsular space through an opening that was inferior to the anteromedial edge of the horizontally oriented component. The defect was curetted and was filled with autogenous graft. Radiographs at four months revealed callus at the site of the fracture.

In the last nineteen reoperations, performed after the possibility of resorption of bone at the periphery of the implant-bone interface by inflammatory tissue had been recognized[23,24,27], we examined the periphery of the interface for evidence of this process. Each hip had circumferential periacetabular bone resorption, resulting in exposure of the outermost, cylindrical edge of the porous mesh. Friable, yellow-tan tissue, which was in continuity with the pseudocapsule of the joint, was interposed at the intra-articular margins of the

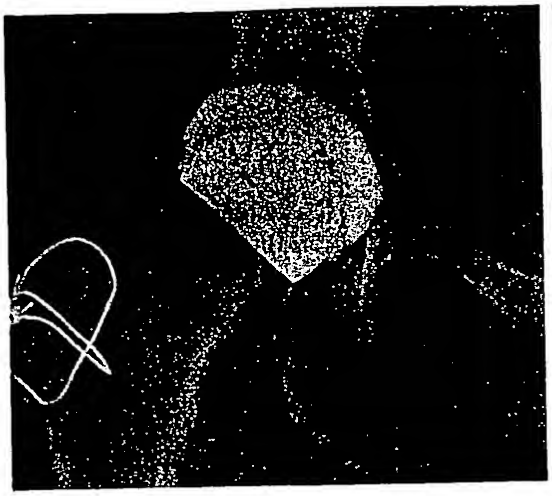

FIG. 4-A

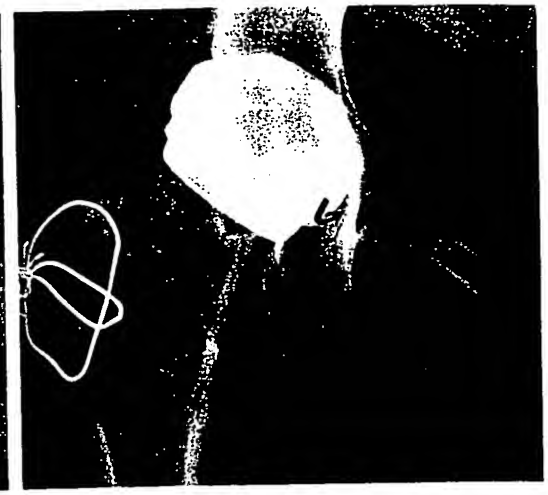

FIG. 4-B

Figs. 4-A through 4-D: Case 10.

Fig. 4-A: Early postoperative anteroposterior radiograph. The acetabular component is relatively horizontal and completely covers the ilium laterally.

Fig. 4-B: Anteroposterior radiograph made before the revision. Osteolysis of the pubis has resulted in a fracture of the superior pubic ramus (straight arrows). There is a communication (curved arrow) between the intracapsular space and the osteolysis.

implant-bone interface in all of the hips.

Review of the radiographs of the remaining sixty-seven well functioning hips revealed osteolysis in an additional nine hips (nine patients) (Group 3, Table I). There were four men and five women, whose average age was fifty-eight years (range, thirty to seventy years). There was no radiographic evidence of loosening of the acetabular component in any hip. The osteolysis was first apparent at an average of twenty-four months (range, nine to thirty-eight months) after the arthroplasty. Two lesions were in the ilium and were associated with an average lateral opening of the acetabular component of 63 degrees, six were in the ischium and were associated with an average lateral opening of 47 degrees (range, 35 to 55 degrees), and one was in the pubis and was associated with a lateral opening of 45 degrees. Two patients had a preoperative degenerative cyst, measuring 0.5 by 1.0 centimeter in each. Both patients had radiographic evidence of osteolysis in the same region after nine and fifteen months, respectively; one (Case

FIG. 4-C

Gross appearance of the articular (concave) surface of the polyethylene liner, retrieved sixty-six months after the implantation. The superi (bearing) surface (arrow) is highly reflective.

11) had a lateral opening of 65 degrees and osteolysis involving the ilium, and the other (Case 13) had a lateral opening of 55 degrees and osteolysis of the ischium.

Retrieved Implants

The bearing surfaces of all of the titanium-alloy femoral components were diffusely burnished, with a variable number of larger scratches. There was more gross damage to the surface of components of prostheses that had had mechanical failure on the acetabular side. Examination of the retrieved polyethylene liners revealed evidence of wear, characterized by loss of the machining marks from manufacturing and a surface that appeared highly reflective to the naked eye (wear-polishing) (Figs. 4-C and 4-D). High volumetric wear of these components has been reported previously[15]. With use of the same method, the rate of volumetric wear of an additional six components was measured; the average rate of wear was 1768 cubic millimeters (range, 763 to 2697 cubic millimeters), with an average rate of 393 cubic millimeters (range, 223 to 514 cubic millimeters) per year.

Randomly oriented scratches and gouges, as well as embedded metallic particles of various sizes (ranging in number from none to more than 100), were identified in all polyethylene components. Some of the metallic debris appeared to be fragments of fiber-metal mesh. The four liners from the acetabular shells that had had mechanical failure had much more embedded metallic debris, located on the backside as well as on the bearing side. Focal areas with loss of machining marks were also seen on the backside. These areas had a surface that was more roughened than reflective. Visual inspection of the outer profile of the liners did not reveal gross deformation of the contour, suggesting that a lesser volume of material had been removed.

Histological Findings

Tissue from the four hips that had had mechanical failure on the acetabular side contained many metallic particles; the histological findings were otherwise similar to those from the other hips. The most consistent finding was variable amounts of necrosis and fibrosis, mixed with sheets of plump macrophages and occasional giant cells that were laden with polyethylene debris of various sizes as well as with occasional metallic particles. Although polyethylene particles as long as 100 micrometers were found, they were relatively rare. Under polarized light, polyethylene particles of approximately one micrometer in length were seen frequently, and a very fine, diffuse birefringence was present in the cytoplasm of these phagocytic cells, indicating the presence of multiple intracellular submicrometer polyethylene particles[11,24].

Three of the four acetabular shells that were revised had bone ingrowth into the fiber-metal mesh. Extensive fibrous ingrowth, but no bone ingrowth, was seen in the remaining component. Radiographs revealed radiolucencies inferiorly and medially, but there appeared

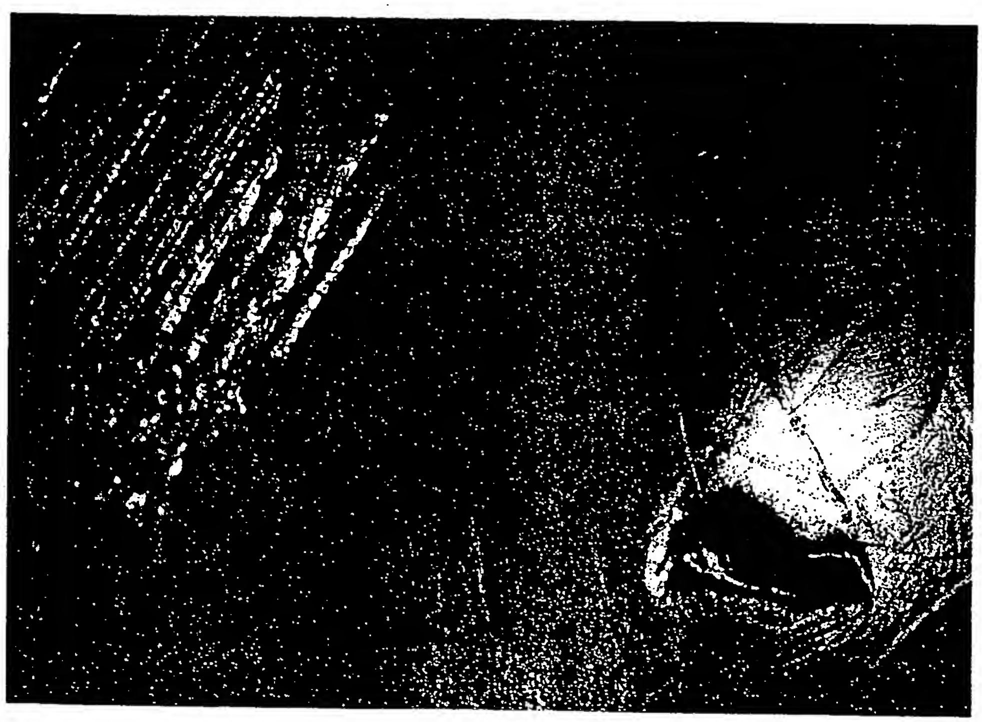

FIG. 4-D

At [illegible] magnification of twenty-five times, several types of surface findings, indicative of different mechanisms of wear that occurred during the [illegible] life of the bearing, are seen. Loss of the machining marks resulted in a smooth, highly reflective polyethylene base (wear-polishing). Random scratches involving both the wear-polished and the machine-marked surfaces are visible. The smooth base of the large pit suggests that it may be an impression left by a hard third body, rather than by a loss of polyethylene.

to be intimate contact of the porous surface with bone superolaterally.

Discussion

The prevalence of radiolucencies at the implant-bone interface has been lower for acetabular components that have been inserted without cement compared with those that have been inserted with cement[23,29]; however, the patterns of bone loss that occur around each group of components may be different. Aggressive, localized bone resorption (osteolysis) may occur more frequently with acetabular components that have been inserted without cement[6,28]. Thus, although fixation has been improved, bone resorption remains a serious problem. The identification of factors associated with the development of such aggressive, localized loss of bone has important implications for the design of the components and the technique of implantation.

The areas of balloon-like osteolysis that we are reporting are more correctly described as involving the pelvis than the acetabulum. These areas are cystic and are filled with a mixture of fluid and friable, necrotic, fibrotic, inflammatory tissue containing particulate wear debris. It appears that the osteolytic process expands into the soft cancellous bone and marrow while being contained by the denser cortical shell of the pelvic bones. Such bone resorption may be clinically silent, and the importance of regularly scheduled radiographic evaluations cannot be overemphasized. Femoral resurfacing components that had a large-diameter bearing surface were used, and the adverse effects of particulate debris occurred relatively early because of the high rate of wear. However, the information regarding the adverse effects of accelerated articular wear on resorption of periacetabular bone has important implications for conventional total hip replacement.

The use of porous-ingrowth fixation appears to have addressed the unacceptably high rate of loosening of the acetabular component that has characterized resurfacing with cement[1,7,11,14]. None of the patients in our series had a reoperation because of loosening of the acetabular component, and none had radiographic evidence of loosening. In this regard, the results with the chamfered-cylinder design are similar to the experience with other porous-ingrowth acetabular components[6,23,25,29]; the intermediate-term rate of fixation of porous-ingrowth acetabular components has been excellent. Reoperation for failure of the femoral side, however, revealed circumferential resorption of bone with invasion of inflammatory tissue into the interface between the implant and bone at the intra-articular margin of the acetabulum. The tissue contained collections of macrophages and occasional giant cells in association with active resorption of bone, similar to that reported around loose acetabular components that were inserted without cement[21,22]. Although metallic particles were found in all specimens and were numerous in specimens that were associated with mechanical failure, most of the particles were polyethylene and were less than one micrometer in length. This is direct evidence that, around rigidly fixed components inserted without cement, there is a process of resorption of periprosthetic bone that is similar to that reported to occur with, and that can result in the loosening of, acetabular components inserted with cement.

The features of an implant, and the specifics of the individual reconstruction (the type of femoral component; the design, position, and technique of insertion of the acetabular component; the presence of fixation screws or pegs; the initial degree of contact of the porous surface with bone; the volumetric wear rate of the polyethylene; the presence and location of preoperative cysts; and stress-shielding) can influence resorption of periacetabular bone[6,23-25,28]. The 17 per cent prevalence (nineteen hips) of osteolysis in the well fixed acetabular components in the present series is alarming and could not be attributed to holes in the metal shell or to transfixing screws. This suggests that other factors are involved in bone resorption around porous-ingrowth acetabular components inserted without cement. The position of the component appears to be important. Difficulty in the reaming of the acetabulum to the chamfered-cylinder geometry resulted in a tendency to insert the component vertically. While the average lateral opening of the acetabular component for all 113 hips was 48 degrees, the nine hips that were associated with osteolysis involving the ilium had a mean lateral opening of 60 degrees. Osteolysis of the ilium was associated with a lateral opening of more than 50 degrees ($p < 0.0001$). Vertical positioning of the component may also be associated with osteolysis of the ilium, as has been reported with use of the PCA total hip prosthesis (Howmedica, Rutherford, New Jersey)[28]. Vertically positioned components wear in the more lateral aspect of the polyethylene liner. Depending on the design of the component, this region may have a reduced thickness of polyethylene (as with the chamfered-cylinder design). In these instances, a decreased contact area and a reduced thickness of polyethylene may result in accelerated wear because of increased stresses on the polyethylene. The average volumetric wear rate of polyethylene with the large-diameter resurfacing components is more than four times greater than that seen in conventional total hip replacements[15]. Wear-polishing of the polyethylene articular surface was the most common finding[13]. This pattern of wear appears to be associated with the generation of the numerous submicrometer polyethylene particles observed in association with bone resorption in our patients, and it probably represents the baseline wear mechanism of a well functioning total hip replacement[18].

An association between the burnished titanium-alloy bearing, particulate titanium debris in the soft tissues, and osteolysis of the neck of the femur has been reported[20]. At a time when such concerns were on the

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-ise, that report highlighted the inadequacies of titanium alloy as a bearing material. What was not recognized was the large amounts of very small particulate polyethylene wear debris[24,26]. In that study[20] and others that involved titanium bearing surfaces, the focus was on metallic debris. Such debris can cause obvious discoloration of tissue, is relatively easily identified in tissue sections, and can more readily be isolated, studied, and quantitated. For these reasons, there has been a substantial amount of work quantitating metallic debris associated with failed reconstructions. These implant systems mated titanium with polyethylene, but polyethylene wear was not assessed, and the very small size of polyethylene debris was not appreciated. We have found that the inflammatory response and bone resorption associated with isolated titanium debris are reduced substantially compared with those found with systems that use polyethylene[2].

The reporting of osteolysis associated with screws or screw-holes through the metal shell of acetabular components inserted without cement[23] has raised concerns that the osteolysis results from particulate debris (possibly generated from the backside [convex] polyethylene surface), which gains access to the ilium through holes in the shell. In a radiographic study with a minimum five-year follow-up of eighty-three hips that were reconstructed with use of a Harris-Galante porous acetabular component (Zimmer) fixed with screws, only one osteolytic lesion of the pelvis was identified (a prevalence of 1.2 per cent)[23]. No pelvic osteolysis was identified in a radiographic study with a minimum four-year follow-up, in which the same type of component, which was press-fit without screws, was used in 122 hips[25]. Thus, the prevalence of pelvic osteolysis after these 205 hip reconstructions was 0.5 per cent[23,25]. A radiographic study with a minimum six-year follow-up revealed pelvic osteolysis after twenty-five of 115 hip reconstructions that had included insertion of a cup with three spikes and no holes[6].

In the present series, it should be emphasized that, in ten of the nineteen patients who had pelvic osteolysis (including six of the nine who had osteolysis of the ilium), there were no holes of any type through the acetabular component (the shell was completely solid). At the time of the reoperation, a communication through an area of bone resorption at the periphery of the implant-bone interface was found to lead to the balloon-like osteolysis. There was evidence of wear of the convex polyethylene surface against the metal shell, but most of the polyethylene wear in these components occurred on the articular (concave) surface. These data and observations indicate that, while there may be advantages to the elimination of holes through the acetabular shell and to more secure fixation and support of the liner by the acetabular shell, neither of these measures will prevent pelvic osteolysis.

In the effective joint space, joint fluid and wear debris will follow the path of least resistance, and focal concentration can result in osteolysis[24]. Compared with acetabular components that have a cement-bone interface, porous-ingrowth acetabular interfaces may offer increased resistance to the ingress of joint fluid and wear debris. A current issue relevant to acetabular reconstruction is the optimization of implant-bone contact and porous ingrowth at the peripheral implant-bone interface in order to decrease bone resorption in this location and to improve long-term fixation of the acetabular component[23,25]. With the unique chamfered-cylinder design, which maximizes peripheral contact through a cylindrical interference fit, there was relatively little bone resorption *along the interface*, as is commonly seen with acetabular components fixed with cement. Most of the bone resorption progressed *away from the interface* into the soft cancellous bone of the pelvis. Our observations indicate that joint fluid and wear debris gain access to pelvic bone through areas of the implant-bone interface without sufficient contact or ingrowth.

Thus, with a porous-coated acetabular component, the path of least resistance may be into the soft, porous, cellular cancellous bone and marrow of the pelvis rather than into an extensively ingrown implant-bone interface. A vertically oriented component can expose the cancellous bone of the ilium to the joint space and predispose the ilium to osteolysis. Similarly, a horizontally oriented component may predispose the pubis or the ischium to osteolysis (Figs. 4-A and 4-B), but because of the small number of horizontally oriented components in this series, we cannot make a more definitive statement.

It is interesting to note that in three patients, pelvic osteolysis developed in areas of pre-existing osteoarthrotic cysts. The osteolysis in these patients developed earlier (at an average of eleven months; range, nine to fifteen months) than in the other sixteen patients who had osteolysis (average, twenty-five months; range, twelve to forty-one months). This suggests that osteoarthrotic cysts may provide a low-resistance pathway for joint fluid and a site for the accumulation of wear debris, making that area susceptible to additional bone loss. A common denominator in the development of osteoarthrotic acetabular cysts and pelvic osteolysis may be the loss or removal of cartilage or dense subchondral bone, or both, which then allows access of joint fluid into the soft cancellous bone of the pelvis. Another phenomenon that may have contributed to the development of the pelvic osteolysis in at least two patients (Cases 1 and 8) is stress-shielding. Loss of bone-mineral density by this mechanism may also predispose to osteolysis.

While particulate debris is clearly associated with osteolytic lesions, there is evidence suggesting that soluble factors in joint fluid, such as inflammatory mediators and proteinases, may also play an important role[16]. Furthermore, the expansile and balloon-like nature of the lesions may be a consequence of joint-fluid pressure and a manifestation of the law of Laplace (which relates tension in the wall of an enclosure to the radius of

the enclosure and the internal pressure (tension = pressure × radius). At the reoperation, several hips in our series had a tense joint effusion. With this type of implant, we have measured peak intra-articular fluid pressures of more than 500 millimeters of mercury (66 kilopascals). The role of joint fluid and joint-fluid pressure in the development of osteolysis is currently under further investigation.

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